Instructions for Use

OSYPKA PACE 203H

Dual-Chamber Temporary Pacemaker

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1 Preface

1.1 General

Read these instructions carefully before using the product described within. Should you have any questions about these instructions or the use of this product, please contact the customer service department before using the product:

Phone: +49 (7623) 7405 - 0

The product may only be placed in service when its proper use can be assured.

According to U.S. Standards, the PACE 203H is a Class III device (21 CFR 862-892 [807.87(c)]).

According to European Standards, the PACE 203H is a Class IIb medical product (Council Directive 93/42/EEC of 14 June 1993 ('Medical Device Directive'), Annex IX).

1.2 Checking the Delivery

Unpack the product and carefully check to see if any damage has occurred in shipment. Check to see if everything was delivered as listed on the shipping list. This includes:

- PACE 203H Dual-Chamber (DDD) Temporary Cardiac Pacemaker / External Pulse Generator
- 9 V Alkaline Battery
- User's Manual and Quick Reference Guide.

Please inform OSYPKA AG immediately if something is missing or damaged. Claims that are filed afterwards cannot be considered.

1.3 Optional Accessories

(Not available in USA and Japan.)

The optionally available medical grade AC power supply (100 ... 240 V / 50 ... 60 Hz) allows the operation of the PACE 203H while conserving battery power.

The optionally available BPI 202™ intra-aortic balloon pump interface provides reliable ECG synchronization for intra-aortic balloon pumps (IABP) which otherwise rely on a surface ECG obtained from three ECG electrodes.

1.4 Writing Conventions of this Manual

In this instruction manual, certain conventions are used. Keys and displays are represented in the text as follows:

- Fixed labeled keys and dials are marked with bold style:

  ON, OFF, Pause, Unlock/Lock

- Texts in the upper display are marked with bold style:

  AUTO, A-TRIG.

- Text in the lower display und soft-labeled keys are marked in italics:

  Main Menu, START

- Helpful hints and notes on the usage of the device and for understanding the modes of operation will be introduced by:

  Notes: …

- Important facts and warnings to be observed are introduced by:

  Warning: …

2 Product Description

The PACE 203H is a dual chamber external cardiac pacemaker with atrial controlled timing for routine temporary heart stimulation. All the usual modes of stimulation are available for treatment of acute brady-arrhythmia and for pre-, intra-, and post-operative stimulation of the heart.

The stimulation parameters are easily adjustable by rotating dials through a wide range of values.

The PACE 203H offers the possibility for atrial overdrive stimulation, or rapid atrial pacing, for terminating supra-ventricular tachycardia. The rate of the overdrive stimulation is adjustable within a wide range and is independent of the selected stimulation rate. The overdrive rate can be determined before and changed during overdrive therapy. If required, overdrive stimulation can be initiated with the touch of a button. The overdrive stimulation is indicated optically and acoustically.

A medical grade AC power supply allows AC operation of the pacemaker while preserving the battery energy. During AC operation a fully charged battery must be in the battery compartment as a backup for AC power failure. *(The AC power supply option is not available in USA and Japan.)*

The functional design of the PACE 203H allows safe and easy operation for all requirements of DDD stimulation.

The PACE 203H offers further the following features:

- During battery changes, stimulation will be maintained for at least 30 seconds (provided fully charged internal capacitors).
- A non-volatile memory keeps any desired stand-by program ready for use, even if the device is shut off.
- A standard program, which can be individualized, is available for each primary pacing mode.
- An emergency program can be “called up” by pressing an emergency key.
- A burst- and a ramp function are available for atrial overdrive-stimulation.
- An Unlock/Lock button protects against accidental change of the set parameters.
- The set parameters and (error) messages are shown on a liquid crystal display.
- The detection of the intrinsic heart activity as well as the emission of stimulation impulses are shown separately by blinking LEDs for both atrium and ventricle. Additionally, a beep-tone can be switched on whenever desired.
- System malfunctions that occur are indicated optically and acoustically.
- A lead surveillance system indicates interruptions and short circuits.

- When a battery change is required, optical and acoustic alerts are provided.
- During dual chamber pacing, an automatic mode for adapting A-V delay, maximum tracking rate (MTR), and PVARP is available.
- An automatic mode for adjusting the sensitivity in both the atrium and ventricle may be choosen.
- A Pause function is available for easy determination and measurement of the patient's intrinsic heart activity.
- The PACE 203H is designed to protect against accidental liquid spills. Insulation between upper and lower housing and the battery compartment lid, as well as sealed dial mountings, allow for a high level of spillage protection.

All further technical functions of the PACE 203H will be described in detail in the following chapters.

3 Indication

The PACE 203H DDD Temporary Cardiac Pacemaker is designed to be used with cardiac stimulation lead systems for temporary atrial, ventricular or A-V sequential stimulation. The PACE 203H has applications where such stimulation modes are indicated for therapeutic, prophylactic, or diagnostic purposes.

Specific indications include, but are not limited to, the following:

- Sick sinus syndrome;
- Bradycardia with congestive heart failure;
- Complete heart block;
- Acute myocardial infarction complicated with heart block;
- Sinus bradycardia;
- Cardiac arrest with ventricular asystole;
- Atrial and/or ventricular ectopic arrhythmia;
- Postoperatively after cardiac surgery;
- Temporary application during implantation or exchange of a permanent pacemaker.

Indication for atrial overdrive stimulation:

- Supra-ventricular tachycardia.

4 Contraindication

There are no contraindications with regards to the use of the PACE 203H for temporary cardiac stimulation for therapy and prevention of arrhythmia. The state of health of the patient, however, can restrict the choice of operational mode and stimulation parameters.

For example, a mode of operation with atrial sensing is not suitable or appropriate when atrial fibrillation occurs. This is due to excessive and chaotic frequency of detected fibrillation waves.

Overdrive-stimulation therapy must only be used in the atrium. Overdrive-stimulation in the ventricle could cause life threatening ventricular fibrillation.

5 Possible Complications

When using an external pacemaker such as PACE 203H, the following complications can arise:

Complication	Result
Infection	Sepsis
Thrombosis and pulmonary embolism	Death
Perforation of the heart	Hemopericardiu. Hemothorax, Cardiac tamponade
Muscle and nerve stimulation	Patient discomfort
Dislocation of lead	System malfunction. Failure to stimulate.
Disconnection or breakage of lead contact problems at connection sites. Insufficient tightening of the collets.	Intermittent or complete failure of effective stimulation and/or sensing.
Dislocation of ventricular lead near atrium.	Atrial oversensing and ventricular inhibition.
Significant rise in the stimulation threshold.	Loss of effectiveness of the stimulation (exit block).
Significant drop of the ECG-signal amplitude after lead dislocation or ingrown lead.	Loss of sensing (entrance-block).
Abnormal pacemaker settings	Erratic rhythm. Compromise in stroke volume / cardiac output
Inappropriately high sensitivity setting. Sensing of R or T waves in the atrium or P waves in the ventricle. Detection of interference (noise, electromagnetic interference).	Ventricular tachycardia, ventricular fibrillation, and death, if not recognized immediately.

Complication	Result
Time mismatch between intracardiac conduction and pacemaker settings.	Pacemaker mediated tachycardia. (In order to prevent this, some decision overrides are implemented in the PACE 203H. However, it is not possible to completely prevent the possibility of a pacemaker mediated tachycardia.)
Overdrive stimulation in the atrium = rapid atrial pacing	Accidental conduction into the ventricle can create ventricular arrhythmia
Battery failure or exhaustion	Failure of impulse emission. Failure to stimulate.
Technical defect in the PACE 203H (failure of components)	Failure or change in the impulse emission, changed (or no) sensing, incorrect displays. Failure to stimulate.
Undetected programming errors	Chaotic rhythm
Erroneous lead connection	Device does not function properly. Chaotic rhythm. Failure to stimulate as intended.
Influence of defibrillation and RF surgery.	See chapter 8 for the effects while simultaneous use of the PACE 203H with defibrillators or electrosurgical instruments.

Table 1: Possible Complications

6 Precautionary Measures and Warnings

The following list presents important precautionary measures and warnings. Further important precautionary measures and warnings will be found in the following chapters.

1. In order to prevent unnecessary complications, the PACE 203H should only be applied and used by medical personnel with extensive experience in cardiac stimulation therapy. Additionally, the person using the device should be thoroughly familiar with the contents of this instruction manual.
2. All lead systems are to be connected to type CF devices only, because of the danger of current being diverted to the heart. Devices that are connected to a main supply pose increased danger for current diversions to the heart.
3. Make sure that all devices in the vicinity of the patient are properly grounded.
4. The stimulation leads provide a direct, low-resistance current path to the heart. Therefore, it is absolutely necessary that the connector plug is not touched with bare hands or come in contact with electrically conductive or wet surfaces. All possible static electricity sources must be kept away from the stimulation system.
5. While the lead is being inserted and connected to the pacemaker, continuous ECG monitoring is mandatory. For emergency situations, a defibrillator should always be available in a ready-to-use state.
6. ECG monitoring should be continued during all times the PACE 203H is in use for the patient to signalize possible complications of different reasons immediately to the medical staff.
7. In either case it is necessary to monitor the patient and to be prepared for a failure of the pacemaker function. A back-up device for the pacemaker must be available.
8. Error messages and conflict warnings of the PACE 203H do not replace an ECG monitoring.
9. During atrial overdrive-stimulation an accidental conduction into the ventricle is possible and may cause ventricular tachycardia. Therefore, continuous ECG-monitoring is mandatory. A defibrillator should always be available and ready-to-use.
10. If the PACE 203H operates in an asynchronous mode the pacing pulses may occur during the vulnerable phase of the patient's intrinsic activity (corresponds approximately in the ECG to the T-wave) and may cause ventricular fibrillation and ventricular flutter, respectively.
11. It is mandatory to continuously monitor the patient and to be prepared for a possible failure or malfunctioning of the pacemaker when the PACE 203H is used in conjunction with electro-surgical instruments or defibrillators.
12. To protect the patient and the pacemaker from current passing through the pacemaker/lead-circuitry caused by defibrillation discharges, the stimulation circuit should always be opened during defibrillation, if possible. Current flows caused by defibrillator discharges can endanger the

patient. High current amplitudes can also damage the pacemaker.

13. If the PACE 203H is to be used for a longer period of time on a patient, the stimulation threshold should be checked from time to time (the first time after a few hours, then daily), since an increase of the threshold may occur.
14. An unnecessarily high sensitivity (small sensitivity value) increases the probability that proper pacemaker functioning will be affected by external interference and the device will switch to asynchronous stimulation (see also chapter 9.22.3). If there are strong electromagnetic fields caused by telecommunication devices (like mobile phones) or other sources an asynchronous mode should be set with a higher than the patient's intrinsic rate.
15. During dual chamber pacing there is an inherent potential risk of cross-stimulation which is a cross-talk of an atrial stimulation or depolarization impulse into the ventricle or vice versa. The PACE 203H is designed in such a way that this cross-talk is minimized. Furthermore, the distance between atrial and ventricular lead system should be not less than 4 cm.
16. Due to differences in the anatomy, electro-physiological conditions and the location of the electrodes, cross-stimulation can, however, not be completely prevented. Therefore, when the device is switched on, or when the stimulation parameters are changed, the user must make sure that no cross-stimulation occurs. If this should happen, one can try to eliminate the effect by adapting the stimulation amplitudes or by exchanging the polarity of the leads. If this is not possible, the pacemaker must, in this special case, be used in a single-chamber mode without connection of the leads of the other channel.
17. The PACE 203H prevents abnormal settings (see chapter 9.22.7).
18. In order to provide continuous operation of the pacemaker during battery changes, the battery must not be left in the device until it is completely drained (see also 9.22.1).
19. If the device is switched off or to stand-by after the request to change the battery appears, the battery must be changed before the pacemaker is turned on again.
20. In case that the PACE 203H is not used for long periods of time, the battery must be removed in order to prevent damage from possible battery acid leakage. (Such damage cannot be compensated under the guarantee).
21. The pacemaker must not be submerged in either water or any other cleaning solution. Do not use any scrubbing powder/liquid on the device.
22. The device must not be sterilized in an autoclave. Sterilization with plasma, ultrasound or gamma radiation is also not allowed. The PACE 203H can be damaged by such procedures.
23. Connector cables, intended for single use, cannot be re-sterilized and reinserted into a patient.
24. Only the manufacturer, or facilities authorized by the manufacturer, can

perform repairs or calibration of the PACE 203H.

25. All automatic settings provided by the PACE 203H are only a guide to assist the user in finding the appropriate settings. It is the responsibility of the operator to determine if these settings are correct.
26. All battery powered devices can lose their function due to normal discharge of the battery. It must also be considered that the pacemaker can stop operating as a result of an unpredictable component failure. The patient should not be left unattended by the medical staff and should always be supervised by a monitoring system.

7 Patient Safety

The temporary cardiac pacemaker PACE 203H meets all applicable international standards for patient safety:

IEC 60601-1	Medical electrical equipment. General requirements for safety
IEC 60601-1-2	Medical electrical equipment. Electromagnetic compatibility
IEC 60601-2-31	Medical electrical equipment. External cardiac pacemakers

In the event that the patient is connected to multiple electrical devices, the sum of leakage currents may exceed the allowable limits.

8 Electromagnetic Compatibility

The temporary cardiac pacemaker PACE 203H meets all applicable international standards with respect to electromagnetic compatibility (EMC).

IEC 60601-1-2	Medical electrical equipment. Electromagnetic compatibility
CISPR 11	Industrial, scientific and medical radio-frequency equipment. Electromagnetic disturbances
IEC 61000	Electromagnetic compatibility

Some sources of radiated emissions may impact the proper function of PACE 203H:

- Electrosurgical instruments operating with radio frequency,
- Devices for diathermy therapy,
- Magnetic resonance imaging (MRI);
- Medical telemetry systems;

Special electromagnetic compatibility (EMC) precautions should be taken when using electrical medical equipment such as the PACE 203H:

A	Portable and mobile RF communications equipment, such as mobile phones, can affect the function of the PACE 203H. Mobile phones with a rated maximum output power of 2 Watt and a transmitter frequency up to 2.5 GHz should be used no closer to any part of the PACE 203H (including patient cables and sensors) than a recommended separation distance of 10 m (30 ft).
B	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30 %.
C	Power frequency magnetic fields should be at levels characteristic of typical commercial or hospital environments.

Please find further information and guidance regarding EMC in chapter 8on page 15.

9 Use and Application of the PACE 203H

9.1 Design

The PACE 203H with its displays, keys, dials and terminals is shown in Figure 1.

.

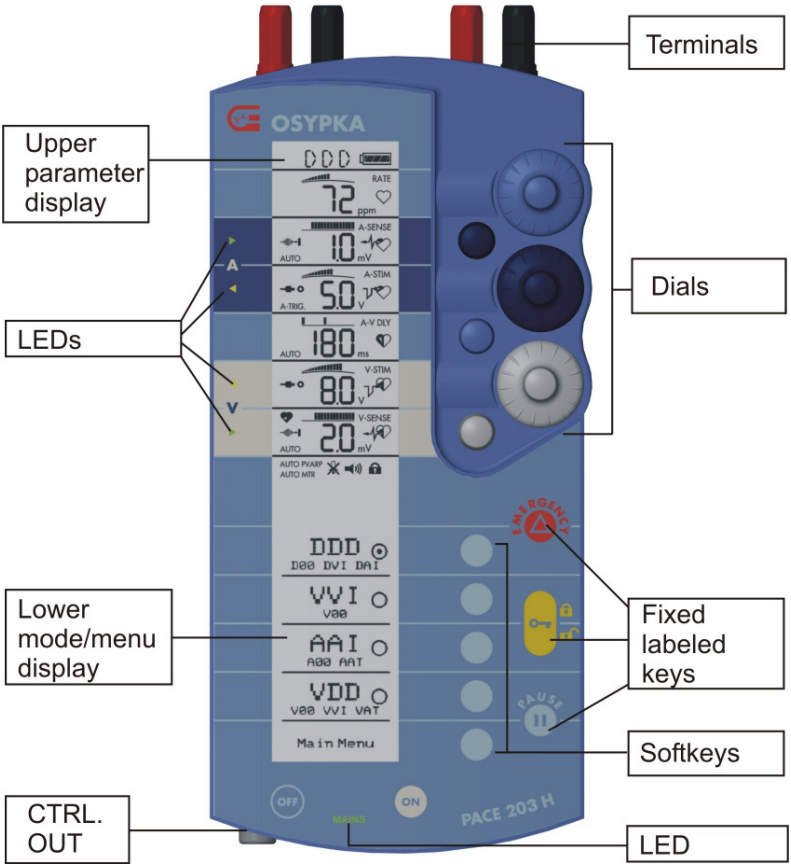


Figure 1 PACE 203H Display Face

Figure 2 Rear View

On the rear side of the device (see Figure 2) there is a metal hanger. This hanger deploys in three snap-in positions. Thus, it can be used as a hanger, as a table-top stand, or it can be folded away. To adjust the hanger, grasp it from the sides and pull away from the pacemaker frame.

The rear side features a battery compartment release button, which opens the battery compartment. The battery compartment is located at the bottom of the device. A button cover prevents the release button from being unintentionally pressed (see chapter 11.2).

9.2 Overview of the Display, Dials and Keys

9.2.1 The Upper Parameter Display

The six parameters, basic rate, atrial sensitivity, atrial pulse amplitude, A-V delay, ventricular pulse amplitude, ventricular sensitivity, as well as the pacing mode code (NBG code) and additional symbols, are continuously displayed as shown in Figure 3.

Figure 3 shows the upper parameter display in DDD mode. Please refer to the indicated paragraphs for detailed information about the symbols.

Parameters are shown only when relevant. In VVI mode, for instance, the upper display will not show an atrial stimulation amplitude, an atrial sensitivity, or an A-V delay.

9.2.2 The Lower Mode / Menu Display

The lower display is used to show selection menus (see section 9.2.5 “The Softkeys and the Menus” on page 20) and various messages. These messages can be informative, as well as alerting the user regarding errors and conflicts

If the lower display is off, then pressing the key **Lock**/**Unlock** turns the display on.

After 2½…3 min, without any user operation (turn of dials or pressing of keys), the lower display disappears for battery power saving.

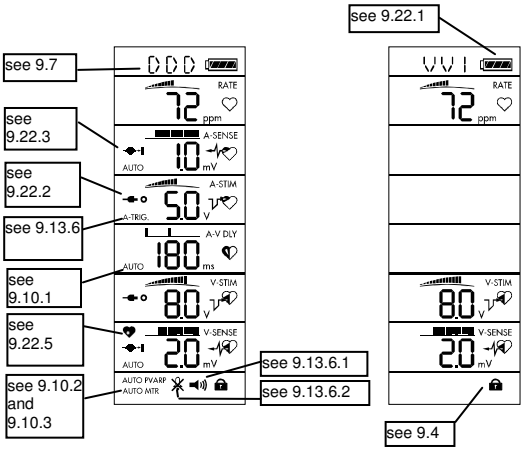


Figure 3: Upper Display

9.2.3 The Dials

There are six dials corresponding to the parameter segments in the upper parameter display. The six parameters basic rate (& atrial overdrive rate), atrial sensitivity, atrial pulse amplitude, A-V delay, ventricular pulse amplitude and ventricular sensitivity are adjustable by rotating these dials (see Table 2).

When the dials are rotated, there is both a tactile (notched click) and acoustic response (beep).

Dial	Function
(HI-) RATE	Adjusting the basic rate and the overdrive stimulation rate.
A-SENSE	Adjusting the atrial sensitivity.
A-STIM	Adjusting the atrial pulse amplitude.
A-V DELAY	Adjusting the A-V delay.
V-STIM	Adjusting the ventricular pulse amplitude.
V-SENSE	Adjusting the ventricular sensitivity.

Table 2: Dials and their functions

9.2.4 The Fixed Labeled Keys

Fixed labeled keys according to Table 3 are implemented.

Key	Function
ON	Turning on the device.
OFF	Turning off the device.
Emergency	Setting emergency stimulation parameters.
Lock/Unlock	Unlocking/Locking the dials and the keys.
Pause	Disable stimulation (as long as pressed)

Table 3: Fixed labeled keys and their functions

9.2.5 The Softkeys and the Menus

For setting of the pacing mode, and other parameters, and functions, five additional keys, so called softkeys, are implemented. These keys are used in conjunction with, and located next to, the lower display. Each softkey selects the option that is displayed adjacent to it in different menus shown in the lower display.

The Mode Menu (Table 4) appears first when the lower display is turned on. The mode selection is located in the top menu level to allow a quick access.

Mode Menu		Key No.
DDD D00 DVI DAI	⊙	1
VVI V00	○	2
AAI A00 AAT	○	3
VDD V00 VVI VAT	○	4
Main Menu		5

Table 4: Mode Menu

All other functions are placed in the second, third or even forth menu level. To access these features, the Main Menu must first be entered by pressing the softkey labeled *Main Menu*. If the lower display is off, then pressing the key **Unlock/Lock** turns the display on. The Main Menu consists of two parts. It appears as shown in Table 5.

Main Menu 1	Key No.
High-Rate	1
Auto	2
Standard	3
Parameters Options	4
↑_	5

Table 5: Main Menu

From here, the High-Rate (overdrive) stimulation, the general parameter/options settings, the parameters of the cardiac resynchronization therapy (CRT), the automatic settings feature, the recall of standard programs, the lead impedance measurement, and further parameter settings and options can be accessed.

Note: Pressing the softkey ↵ in any menu always returns to the Main Menu.

9.2.6 Display Backlight

Both the upper and lower displays are backlit. The backlight is deployed as long as the device is unlocked.

After 30 seconds without any user operation (rotation of dials or pressing keys), the backlight is automatically turned off for battery power saving. This occurs in parallel upon locking the dials and keys.

If the battery voltage decreases below a specified battery depletion level, the backlight is automatically deactivated and will not be turned on again until the battery has been replaced.

9.2.7 LEDs for Sensing and Stimulation

To the left of the upper display there are four LEDs for indicating atrial and ventricular sensing and stimulation events. The LEDs for indicating sensing flash green and those for indicating stimulation flash yellow.

All LEDs appear brightly shortly after turning on the PACE 203H to verify that they are operational.

9.2.8 Acoustic Indications

Key pressing results in a high-frequency acoustic signal (beep).

Warnings are acoustically indicated by three successive short high frequency acoustic signals (beeps), whereas errors are indicated by one long high frequency signal (long beep).

If the Beep feature is enabled (see chapter 9.12.5.1), sensing and stimulation events are acoustically indicated (beep). Sensing and stimulation are indicated by a different high frequency signal (beep). Specifically, sensing occurs with a lower frequency signal than stimulation.

9.3 Powering On the PACE 203H

The PACE 203H is powered on by pressing the key labeled **ON**

Subsequently, the PACE 203H performs a self-test.

If the device was set to Stand-by (see chapter 9.5) it starts operation immediately with the last saved parameter setting.

If the device was OFF, the key **Lock**/**Unlock**, which is located to the right of the softkeys, must be pressed and released to indicate that it is functioning properly. The PACE 203H indicates this by the schematized key symbol shown in the lower display (Table 6 and Table 7).

Press Lock/Unlock key request
Press
Version n.nn
yyyy/mm/dd

Table 6: Press Lock/Unlock Key Request

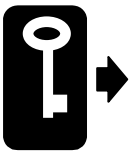
Release Lock/Unlock key request
Release

Version n.nn
yyyy/mm/dd

Table 7: Release Lock/Unlock Key Request

Note: Version n.nn indicates the hardware and/or software version of the device, and yyyy/mm/dd the corresponding release date (Year/Month/Day).

When the key **Unlock**/**Lock** has been pressed and released, the PACE 203H begins to function with the Turn-on program (see chapter 9.11.5). Upon shipping from the manufacturer, a DDD mode with high sensitivity and moderate stimulation amplitudes is preset. This setting provides safe therapy for most pacing situations (see Table 40). The Turn-on program, however, may be customized according to the physician's preferences.

The language setting (see chapter 9.12.5.4) and acoustic indication of sensing and stimulation (see chapter 9.2.8) will remain unchanged during power off.

Note: If the indication to press and release the key **Unlock**/**Lock** is not followed within 30 sec, an error message

Startup timeout
(Press Unlock)

will appear, and the device will switch off. This prevents discharge of the battery, if the key labeled **ON** has been pressed accidentally.

Note: Please do not press any key during the self-testing after turning on the PACE 203H. Among other tests, a key check is performed during this period. If a key is pressed, a request will be indicated as follows

Release all keys

If the operator is not in compliance with this request, or if a key is ‚stuck', the message:

Keyboard error

will appear in the lower display after 10 seconds.

9.4 Locking/Unlocking the PACE 203H

In order to prevent an accidental change of pacing parameters, the device will be locked automatically, if no control has been turned or no key has been pressed for 30 sec.

If the device is locked, pressing the key **Lock**/**Unlock** performs an unlock function. If the device is unlocked, pressing the key **Lock**/**Unlock** disables any dials and menu operation of the PACE 203H.

Whether the device is locked or unlocked, these conditions will be continuously indicated by the lock symbol (Figure 4) in the upper display.

Figure 4: Lock Symbol

If a key is pressed, or a dial is rotated while the device is locked, a warning beep will be emitted and the lock symbol will blink for 2 seconds.

Note: For High-Rate Stimulation Standby (see chapter 9.10) the time of operating freedom is 60 seconds after last operation.

9.5 Powering Off The PACE 203H

The PACE 203H is powered off by pressing the key labeled **OFF**.

In order to prevent powering off the device by mistake, a menu (Table 8) appears in the lower menu with the softkeys labeled *Off* and *Stand-by*.

Power-Off Menu	Key No.
Off (no storage)	1
	2
Stand-by (store data)	3
	4
↑_	5

Table 8: Turn-off Menu

Upon selecting Off (no storage) by pressing the corresponding softkey, the PACE 203H switches off without storage of the actual settings, prompting the message “Off (no storage)“.

Upon selecting “*Stand-by (store data)*” by pressing the corresponding softkey, the PACE 203H stores the actual settings, prompting the message, “Stand-by (store data)”, and then switches off. The PACE 203H does not consume any battery power in the Stand-by mode.

When the PACE 203H is powered on from the Stand-by mode, it will, after switching on, function with these prior settings, and not with the Turn-on program.

The PACE 203H switches off with a short acoustic signal (beep).

9.6 Modes of Operation

The following terms are defined:

The **beat-to-beat interval** (a pacemaker parameter) is the programmed interval of a complete pacing cycle, measured in milliseconds (ms). It is determined as the inverse of the basic rate.

Wenckebach behavior is always activated in atrioventricular modes incorporating atrial sensing. In case of high spontaneous intrinsic atrial rates, the P-V delay will be prolonged in order to prevent high ventricular stimulation rates. This function limits the ventricular rate to the so-called **Maximum Tracking Rate (MTR)**. As a consequence, Wenckebach behavior intermittently blocks the conduction of intrinsic atrial beats to the ventricular chamber.

The **A-V delay** (a pacemaker parameter) is the programmed atrioventricular pacing interval, initiated by an atrial stimulus.

The **P-V delay** (a pacemaker parameter) is the programmed time interval between atrial sensing (P wave) and the ventricular stimulus. The P-V delay can be interpreted as a programmable conduction delay window. It is determined by the A-V delay and by the Maximum Tracking Rate (MTR).

The **A-V interval** is the measured time interval between a sensed or paced atrial event and the subsequent ventricular sensed or paced event. In case of

spontaneous ventricular depolarization, the A-V interval is shorter than the programmed A-V delay.

The **V-A delay** (a pacemaker parameter) is the programmed ventriculoatrial interval, initiated by a sensed or paced ventricular event. Known also as the Atrial Escape Interval, it is the interval from a sensed or paced ventricular event to an atrial paced event. Every cycle, the V-A delay is calculated as the difference between the set beat-to-beat interval and the A-V interval.

Atrial triggering means that a detected P-wave causes an atrial stimulus. The programmable options for atrial triggering are OFF or ON.

The **blanking period** is defined as the time during and after a sensed or paced event when the sensing channel and/or the opposite channel of an atrioventricular pacemaker are insensitive. The purpose is to avoid sensing of late potentials and sensing the event of one channel in the opposite channel (crosstalk). Thus, during the blanking period, no events are recognized.

Refractory period is a set time in the pacemaker, in which a signal in the respective channel will be recognized but not tracked or does not cause inhibition.

Sensing phase is the period of time in which a signal that occurred in the respective channel will be recognized, interpreted as intrinsic, and tracked. Thus, this is the period outside blanking or refractory periods.

The **post-ventricular atrial refractory period**, or **PVARP** (a pacemaker parameter), is the period after a sensed or paced ventricular event during which the atrial sensing circuit is refractory. Thus, any atrial event occurring during PVARP will not be sensed by the atrial sensing circuit. In biventricular stimulation the PVARP starts after the second ventricular stimulus.

9.6.1 Ventricular Asynchronous (V00) Pacing

Ventricular asynchronous (V00) pacing is the simplest of all pacing modes because there is no sensing and no mode of response. The ventricular pacing stimuli occur at the programmed rate, regardless of any intrinsic cardiac event.

9.6.2 Atrial Asynchronous (A00) Pacing

Atrial asynchronous (A00) pacing behaves exactly like V00, but the pacing stimuli occur in the atrium. The atrial pacing stimuli occur at the programmed rate, regardless of any intrinsic cardiac event.

9.6.3 A-V Sequential Asynchronous (D00) Pacing

Dual-chamber, or A-V sequential asynchronous (D00), pacing provides atrial and subsequent ventricular stimuli with a fixed, programmed delay. The pacing stimuli occur at the programmed rate, regardless of any intrinsic atrial or ventricular events.

9.6.4 Ventricular Inhibited (VVI) Pacing

Ventricular inhibited (VVI) pacing incorporates sensing on the ventricular channel, and pacemaker output is inhibited by a sensed ventricular event. In VVI mode, the PACE 203H is refractory for a period after a paced or sensed ventricular event, the ventricular refractory period. Any ventricular event occurring within

the ventricular refractory period is not sensed. Any ventricular event occurring outside the ventricular refractory period is sensed and resets the timing of the pacemaker to the beginning of a new beat-to-beat interval.

9.6.5 Atrial Inhibited (AAI) Pacing

In the absence of intrinsic activity, ventricular or atrial stimulation impulses will be given with the set basic rate. The recognition of a P-wave in AAI mode in the pacemaker's sensing phase inhibits the delivery of the next stimulation impulse, resets the timing of the pacemaker to the beginning of the beat-to-beat interval and starts the refractory period.

9.6.6 Atrial Synchronous (P-Tracking) (VDD) Pacing

In atrial synchronous (P-tracking) (VDD) pacing mode, the PACE 203H stimulates only in the ventricle, senses in both atrium and ventricle, and responds both by inhibition of ventricular output by intrinsic ventricular activity and by ventricular tracking of P waves.

A sensed P wave initiates the P-V delay. During the P-V delay, the atrial channel is refractory. At the end of the P-V delay, a ventricular stimulus is delivered if no intrinsic ventricular activity has been sensed, that is, P wave tracking. Ventricular activity, paced or sensed, initiates the PVARP and the V-A delay.

If no P wave activity occurs during the V-A delay, the A-V delay is initiated. During the A-V delay, the atrial channel is refractory. If no R-wave activity occurs during the A-V delay, the PACE 203H delivers a ventricular pacing stimulus upon termination of the A-V delay.

9.6.7 Dual-Chamber Pacing and Sensing with Inhibition and Tracking DDD

This pacing mode provides dual-chamber pacing and sensing with inhibition and atrial tracking.

If intrinsic atrial and ventricular activity occur before the beat-to-beat interval terminates, both channels are inhibited and no pacing occurs.

If a P wave is sensed before the V-A interval is completed, output from the atrial channel is inhibited. The A-V delay is initiated. If no ventricular activity is sensed before the A-V delay terminates, a ventricular pacing stimulus is delivered, that is, P-synchronous ventricular pacing.

If no atrial activity is sensed before the V-A delay is completed, an atrial pacing stimulus is delivered, which initiates the A-V delay. If intrinsic ventricular activity occurs before the termination of the A-V delay, the ventricular output from the PACE 203H is inhibited, that is, atrial pacing. If no intrinsic ventricular activity occurs before the termination of the A-V delay, a ventricular pacing stimulus is delivered, that is, A-V sequential dual-chamber pacing.

The A-V Sequential, Atrial Inhibited (DAI) Pacing

A-V sequential, atrial inhibited (DAI) pacing provides pacing in both the atrium and the ventricle but sensing only in the atrium. This mode is implicitly selected by setting first the DDD mode and, second, the ventricular sensitivity to infinite ("–.–"). Thus, sensing in the ventricular channel is disabled.

The DAI mode may be useful in situations where no ventricular sensing is possible (for instance, because of inter-

ference), or when A-V synchrony must be maintained upon a complete A-V block.

9.6.8 The A-V Sequential, Ventricular Inhibited (DVI) Pacing

A-V sequential, ventricular inhibited (DVI) pacing provides pacing in both the atrium and the ventricle but sensing only in the ventricle. This mode is implicitly selected by setting first the DDD mode and, second, the atrial sensitivity to infinite ("–.–"). Thus, sensing in the atrial channel is disabled.

Note: With the DVI mode (implicitly) set, the following exceptions are taking place:

1) The PACE 203H - specific algorithm for determining extrasystoles is disabled. In DVI mode, the PACE 203H cannot differentiate between high intrinsic rates and occurrences of extrasystoles, because the atrial sensing is disabled.
2) If another R-wave is detected during the V-A delay, the V-A delay will be initiated with a value equal to the difference between the beat-to-beat interval and the A-V delay.

9.6.9 Atrial Sensing Atrial Synchronous (P-Tracking) (VAT) Pacing

In atrial synchronous (P-tracking) (VDD) pacing mode, the PACE 203H stimulates only in the ventricle but senses in the atrium only. If intrinsic atrial activity occurs, a ventricular stimulus is delivered after the P-V delay.

This mode is implicitly selected by first setting the VDD mode and, second, the ventricular sensitivity to infinite ("–.–"). Thus, sensing in the ventricular channel is disabled.

The VAT mode may be useful in situations where no ventricular sensing is possible (for instance, because of interference), or when A-V synchrony must be maintained upon a complete A-V block.

9.6.10 Non-Pacing Mode 0D0 (Pause)

In this mode, sensing is enabled in all channels but not pacing. The PACE 203H is 'listening' to intrinsic atrial and ventricular events only.

The 0D0 mode is utilized to check the patient's intrinsic activity (see chapter 9.15) or to get initial values for the Auto Sense feature (see chapter 9.9.4). It must be used with **great caution** on patients depending on a pacemaker.

9.6.11 Atrial Trigger Modes DDD+AT and DAT

If Atrial Trigger option (see chapter 9.12.5.3) is activated, an atrial stimulus is delivered any time an atrial activity is sensed, and with the atrial channel not being refractory.

The Atrial Trigger is enabled when either AAI (→ AAT) or DDD (→ DDD+AT) or DAI (→ DAT) modes are set.

9.7 Changing the Mode of Operation

If the lower display is switched on, it always displays the Mode Menu first. Each of the primary modes (DDD, VVI, AAI, VDD) can now be selected by the touch of the corresponding softkey (Table 9).

If the lower display is off, it can be turned on pressing the key **Unlock**/**Lock**. In the event that another menu is displayed, pressing the ↑_ softkey will switch to the mode menu immediately.

Mode Menu		Key No.
DDD D00 DVI DAI	⦿	1
VVI V00	○	2
AAI A00 AAT	○	3
VDD V00 VVI VAT	○	4
Main Menu		5

Table 9: Mode Menu

The modes D00, V00, A00, DVI, DAI and VAT are set by selecting the “primary" mode (DDD, VVI, AAI, VDD) and setting the sensitivity in the respective channel(s) to infinite, which will be displayed as "–.–". Table 10 shows the resulting supplementary modes, if the sensitivity is set to infinite.

Primary Mode	Sensitivity	Resulting Mode
DDD	A-Sensitivity → "–.–"	DVI
DDD	V- Sensitivity → "–.–"	DAI
DDD	A + V- Sensitivity → "–.–"	D00
VVI	V- Sensitivity → "–.–"	V00
AAI	A- Sensitivity → "–.–"	A00
VDD	A- Sensitivity → "–.–"	VVI
VDD	V- Sensitivity → "–.–"	VAT
VDD	A + V- Sensitivity → "–.–"	V00

Table 10: Supplementary Mode

The selected mode is indicated with its NBG code[1] in the upper display. In the new mode, the PACE 203H continues to

[1] Bernstein AD, Camm AJ, Fletcher RD, et al. The NASPE/BPEG generic pacemaker code for antibradyarrhythmia and adaptive-rate pacing and antitachyarrhythmia devices. Pacing Clin Electrosphysiol 1987; 10: 794-799

work with the parameters set before the mode change.

Note: In case of a change from a single to a dual chamber mode or from one chamber mode to another chamber mode (for instance VVI→AAI), the last used parameters are adopted. If the Turn-on program (see chapter 9.11.5), has been re-defined to a single chamber mode, in case of a first change of such kind, the parameter set will be complemented from the standard program of the new mode.

The enabling of the atrial trigger function in the AAI and DDD modes is described in chapter 9.12.5.3.

A non-pacing mode (0D0) is accessible by pressing the key labeled **Pause** (see chapter 9.15).

Note: A standard program can be stored for each primary mode. These standard programs may be defined by the user (see chapter 9.11).

Note: If conflicts (because of abnormal settings) occur as a result of a mode change, the PACE 203H will make use of its Automatic setting feature to solve the problem (see chapter 9.22.7 and 9.9)

9.8 Adjustment of Rate, Stimulation Amplitude, Sensitivity and A-V Delay

One rotary dial is assigned to each of the parameters. Table 11 shows the function of each dial.

Dial	Function
RATE	Basic rate
A-SENSE	Atrial sensitivity
A-STIM	Atrial stimulation amplitude
A-V DLY	Atrio-ventricular delay
V-STIM	Ventricular stimulation amplitude
V-SENSE	Ventricular sensitivity

Table 11: Rotary Dial functions, listed in order from top to bottom

The actual values of the parameters, and the corresponding bar diagrams indicating signal intensity or magnitudes, are located in the upper display, which is always turned on. These bar diagrams indicate the set value within its range.

In order to change a parameter, or parameters, the dials must be unlocked by pressing the key **Unlock**/**Lock** (if the PACE 203H is not yet unlocked).

Rotating the rate, amplitude, or A-V delay dials clockwise increases the parameter value. In contrast, counterclockwise rotation decreases the parameter value

Rotating a sensitivity dial clockwise increases the sensitivity value, i.e. de-

crease the sensitivity. In contrast, counterclockwise rotation decreases the sensitivity value, i.e. increases the sensitivity

If a maximum or minimum value is reached, further rotation of the dial is disregarded.

Each parameter change is visualized on the upper display, both as a number and as a bar diagram

Any change of the parameters will become effective after the next sensing or stimulation event.

Several parameters are allowed to change simultaneously.

If a parameter has no pacing function in the mode selected, for example, A-Sense in the VVI mode, the corresponding section in the upper display is blanked. If a dial, belonging to parameter without pacing function in the mode selected, is set, the respective, previously blanked section will be switched on. A numeric value will be briefly displayed, whereupon it will disappear in approximately two seconds.

9.8.1 Adjustment of Basic Rate

Rotating the **RATE** clockwise will increase the basic rate in the range shown in Table 12. The actual rate value and the intensity bar diagram can be seen in the upper display. The intensity bar diagram enlarges from left to right with rate increase.

Parameter	Adjustable Values	Unit
Rate	30 (2) 220	ppm

Table 12: Adjustable Values for Rate (step width in parenthesis)

In order to avoid unintentional settings of high stimulation rates, the desire to increase the stimulation rate from 150 ppm (Table 13) and then from 180 ppm must be confirmed.

Confirmation Message	Key No.
Rate > 150 ppm ?	1
	2
YES →	3
NO →	4
	5

Table 13: Confirmation message when increasing the rate higher than 150 ppm.

Each time the stimulation rate is increased (by rotating the dial **RATE** clockwise) higher than 150 ppm, the message “Rate > 150 ppm?” appears and must be confirmed with *YES* in order to increase the rate from 150 ppm. *NO* abandons the intention to increase the stimulation rate, and the message dis-

appears. Once the threshold of 150 ppm is passed, increases of the stimulation rate in the range beyond 150 ppm and less or equal than 180 ppm require no confirmation.

Note: The safety feature "protection against abnormal settings" (see chapter 9.22.7) prevents increasing the basic rate to a value larger than the MTR in DDD, VDD, DAI, VAT and DAT mode. Limiting the basic rate value is accompanied by a transient warning message in the lower display.

9.8.2 Adjustment of Stimulation Amplitude

By rotating the **A-STIM** dial or the **V-STIM** dial clockwise the stimulation amplitude will be increased in the range shown in Table 14.The actual stimulation amplitude value and the intensity bar diagram can be seen in the upper display. The intensity bar diagram enlarges from left to right with amplitude increase.

Parameter	Adjustable Values	Unit
Stimulation Amplitude	0.1 (0.1) 2.0 2.0 (0.2) 6.0 6.0 (0.5) 12.0 12.0 (1.0) 18.0	V

Table 14: Adjustable Values for Stimulation Amplitude (step width in parentheses)

9.8.3 Adjustment of Sensitivity

By rotating the **A-SENSE** dial or the **V-SENSE** dial clockwise, the sensitivity value (mV value) increases. This indicates that the sensitivity will decrease. The actual sensitivity value and the parameter intensity bar diagram can be seen in the upper display. The parameter intensity bar diagram diminishes from left to right, when the sensitivity value is increased (sensitivity is decreased). If the minimum sensitivity is reached, the value "infinite" is indicated by "–.–" in the display, and a mode change occurs. This is indicated by the pacing mode code, visible in the upper display (see chapter 9.7).

By rotating the **A-SENSE** dial or the **V-SENSE** dial counterclockwise, the sensitivity value (mV value) decreases. This indicates that the sensitivity value increases. The parameter intensity bar diagram expands from the right to left side.

The sensitivity is adjustable in the range and with the steps shown in Table 15.

Parameter	Adjustable Values	Unit
Atrial Sensitivity	0.2 (0.1) 2.0 2.0 (0.2) 5.0 5.0 (0.5) 10.0 10.0 (1.0) 20.0 –.– (= no sensing)	mV
Ventricular Sensitivity	1.0 (0.1) 2.0 2.0 (0.2) 5.0 5.0 (0.5) 10.0 10.0 (1.0) 20.0 –.– (= no sensing)	mV

Table 15: Adjustable Values for Sensitivity (step width in parenthesis)

Warning: Increasing the mV values indicates decreasing the sensitivity. An atrial value of 0.2 mV and a ventricular value of 1.0 mV represent the highest sensitivity in the respective channels. The value "infinite" results in an asynchronous mode for the corresponding

channel. An inhibition of the stimulation pulse in this channel is not possible.

9.8.4 Adjustment of A-V Delay

By rotating the **A-V DLY** dial clockwise, the A-V delay will become extended within the range shown in Table 16. The actual A-V delay and the parameter intensity bar diagram can be observed in the upper display. The parameter intensity bar diagram corresponds to the A-V delay. The leftmost bar represents the timely occurrence of the atrial event and is always displayed. A second bar represents the timely occurrence of the ventricular event and is "shifted" right or left, related to the increase or decrease the A-V delay, respectively.

Parameter	Adjustable Values	Unit
A-V Delay	5, 10 (10) 400	ms

Table 16: Adjustable Values of A-V Delay (step width in parenthesis)

The P-V delay (PVD) is coupled with the A-V delay (AVD). Adjusting the AVD also sets the PVD. By default the difference AVD-PVD is equal to 30 ms, that is, PVD is 30 ms shorter than AVD.

Note: When atrial Auto Sense is enabled, the A-V delay and P-V delay are limited to a minimum of 30 ms. This is because Auto Sense requires a specified time to measure the intrinsic atrial activity. In case the atrial Auto Sense is enabled, and the A-V delay was set to a value smaller than 30 ms, then the A-V delay will be automatically extended to 30 ms. This action is indicated by a transient informative message in the lower display (see also chapter 9.9.4).

Note: Because of its safety feature "protection against abnormal settings" (see chapter 9.22.7), the PACE 203H prevents increasing the A-V delay to a value, which would not guarantee a minimum atrial sensing phase in dual chamber demand modes, or a minimum V-A interval in the D00 mode, respectively. The limitation of the A-V delay value will be indicated by a transient warning message in the lower display.

9.9 Using the Automatic Features

The PACE 203H offers the capability for automatic setting of A-V delay, PVARP, and maximum tracking rate (MTR), with the setting of rate as well as for automatic adjustment of sensitivity.

To enable these features, the Auto Menu must first be entered by pressing the softkey labeled *Main Menu* and then the softkey labeled Auto.

If the lower display is off, then pressing the key **Unlock**/**Lock** turns it on. The Auto Menu appears as shown in Table 17.

Then, with the corresponding keys, one or more of the automatic features can be enabled or disabled individually.

Auto Menu		Key No.
Auto AVD	☑	1
Auto PVARP	☑	2
Auto MTR	☑	3
Auto Sense		4
↑_		5

Table 17: Auto Menu

9.9.1 Automatic Setting of A-V Delay with the Setting of Rate

If this feature is enabled, the PACE 203H automatically adjusts the A-V delay with the setting of the basic rate.

To activate Auto A-V Delay, the softkey labeled *Auto AVD* in the *Auto Menu* has to be pressed. The corresponding check box then gets checked.

The PACE 203H then adjusts the A-V delay depending on the basic rate according to the formula in Table 18. and rounded to the nearest manually adjustable value (see chapter 9.8.4). In the corresponding **A-V DLY** segment in the upper display the label AUTO indicates that the Auto A-V delay feature is activated. The calculated value for the A-V delay is also indicated numerically.

Auto A-V Delay can be deactivated either via the Auto menu or simply by rotating the (unlocked) **A-V DLY** dial a few clicks (approximately a quarter of one revolution).

Automatic A-V Delay	Range	Unit
A-V Delay = 290 – (1.5 x Rate/ppm)	50...250	ms

Table 18: Automatic Setting Equation for A-V Delay

If the **A-V DLY** dial has been rotated to deactivate Auto A-V delay, the transient message

Auto AVD
turned off

appears in the lower display accompanied by a short beep, and **AUTO** disappears from the upper display.

To deactivate Auto A-V Delay in the Auto menu, the softkey labeled *Auto AVD* must be pressed again. This causes the check mark to disappear from the corresponding check box and **AUTO** from the upper display.

9.9.2 Automatic Setting of PVARP with the Setting of Rate

If this feature is enabled, the PACE 203H automatically adjusts the postventricular atrial refractory period (PVARP) with the setting of the basic rate.

To activate Auto PVARP, the softkey labeled *Auto PVARP* in the *Auto Menu* must be pressed. The corresponding check box then gets checked.

The PACE 203H now adjusts the PVARP depending on the basic rate according to the formula in Table 19 and rounded to the nearest manually adjustable value (see chapter 9.12.1). In the

upper display the label **AUTO PVARP** indicates that the Auto PVARP feature is activated.

Automatic PVARP	Range	Unit
PVARP = 330 – (0.75 x Rate/ppm)	100…500	ms

Table 19: Automatic setting formula for PVARP

To deactivate Auto PVARP, the softkey labeled *Auto PVARP* in the Auto menu must be pressed again. This causes the check mark to disappear from the corresponding check box and **AUTO PVARP** from the upper display. The PVARP & MTR setting menu appears showing the actual value which provides the opportunity to adjust a new value manually (see chapter 9.12.1).

Note: The PVARP of the PACE 203H is divided in two parts: an absolute part and a relative part. In the absolute part (which is 100 ms long), no atrial events are recognized. In the relative part (the remaining) atrial events are registered, but not tracked. This algorithm prevents the misinterpretation of ventricular events after premature atrial events as extrasystoles (PVCs), as described in chapter 9.22.5.

9.9.3 Automatic Setting of MTR with the Setting of Rate

If this feature is enabled, the PACE 203H automatically adjusts the Maximum Tracking Rate (MTR) with the setting of the basic rate.

To activate Auto MTR, the softkey labeled *Auto MTR* in the *Auto Menu* must be pressed. The corresponding check box then gets checked.

The PACE 203H then adjusts the MTR to a value 34 ppm higher than the basic rate, but with a minimum of 100 ppm and a maximum of 230 ppm, according to the formula and the range in Table 20. In the upper display the label **AUTO MTR** indicates that the Auto MTR feature is activated.

Automatic MTR	Range	Unit
MTR = Rate + 34	100…230	ppm

Table 20: Automatic setting formula for MTR

To deactivate Auto MTR, the softkey labeled *Auto MTR* in the *Auto Menu* must be pressed again. This causes the check mark to disappear from the corresponding check box and the label **AUTO MTR** in the upper display. The MTR setting menu appears showing the actual value which provides the opportunity to input a new value manually (see chapter 9.12.2).

9.9.4 Automatic Adjustment of Sensitivity (Auto Sense)

9.9.4.1 How the Auto Sense Function Works

The Auto Sense function automatically adjusts the PACE 203H sensitivity to maintain an approximate 3:1 sensing safety margin, potentially reducing the number of under/over-sensing episodes. This feature may also reduce the need to manually determine the sensitivity threshold (see chapter 9.17).

The Auto Sense function is different from the other automatic functions in that the automatic sensing value is not calculated from another parameter. The PACE 203H adapts the sensing value continuously to the patient's intrinsic heart activity. For this intrinsic activity, which is detected in the sensing phase of the respective channel, the amplitude is measured and the sensitivity value of the pacemaker is adapted to maintain the 3:1 sensing safety margin.

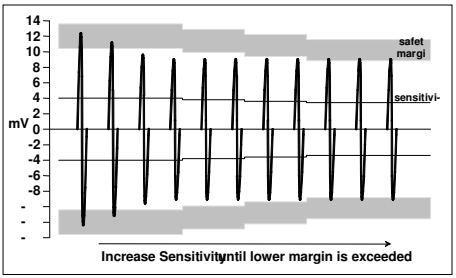


Figure 5: The Auto Sense function increases sensitivity

Figure 5 shows an example in which the sensitivity is increased (i.e. sensitivity value is decreased) to maintain an appropriate safety margin when the EGM amplitude drops.

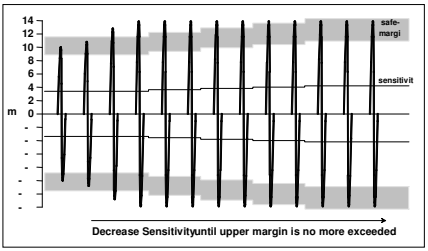


Figure 6: The Auto Sense function decreases sensitivity

Figure 6 shows an example in which the sensitivity is decreased (i.e. sensitivity value is increased) when the EGM amplitude goes up. An appropriate safety margin is kept without working with unnecessarily high sensitivity, which may promote noise detection.

9.9.4.2 Important Notes Using the Auto Sense Function:

Because the intrinsic activity of the patient's heart determines the sensitivity value, the Auto Sense feature can, of course, only be used in a patient who has such intrinsic activity.

Auto Sense cannot be used together with Atrial Trigger, because the triggered stimulation prevents proper measurement of the intrinsic activation (see also 9.12.5.3)

Auto Sense requires a specific time to measure the intrinsic atrial activity. P-V

delay is therefore limited to a minimum of 30 ms when atrial Auto Sense is activated. Because A-V delay cannot be shorter than P-V delay it is also limited to 30 ms. In case atrial Auto Sense is enabled, and the A-V delay was set to a value smaller than 30 ms, then the A-V delay will be automatically extended to 30 ms. This action will be indicated by a transient informative message in the lower display (see also 9.8.4).

9.9.4.3 Activation of Auto Sense

Because the Auto Sense algorithm requires sensed intrinsic atrial or ventricular events to become operational, an initial appropriate sensing value is required to enable the Auto Sense feature. The following procedure has been established to obtain this initial value:

To enter the Auto Sense Menu the softkey labeled *Auto Sense* in the Auto Menu must be pressed (see Table 21).

Auto Sense Menu		Key No.
		1
Atrial Auto Sense	☐	2
Ventricular Auto Sense	☐	3
		4
↑_		5

Table 21: Auto Sense Menu

The softkey labeled *Atrial Auto Sense* and/or *Ventricular Auto Sense* must be in order to enable or disable the Auto Sense feature for the atrial and/or ventricular channel (Table 21).

If Auto Sense is being enabled in a channel where it was not activated before, a check mark appears in the respective checkbox. The checkbox then starts blinking, and the request to press and hold the softkey labeled Initiate is indicated in the lower display.

Table 22 illustrates this scenario, if Auto Sense is enabled in both channels.

Auto Sense Menu		Key No.
		1
Atrial Auto Sense	☑	2
Ventricular Auto Sense	☑	3
Initiate (Press & Hold)		4
↑_		5

Table 22: Auto Sense Menu (channels selected, initialization request)

When the softkey labeled *Initiate* is pressed, the PACE 203H stops pacing as long as this key is held down. However, the PACE 203H continues to sense and attempts to detect a regular intrinsic activation of the patient's heart. While doing this, the lower display appears as shown in Table 23. A flashing heart symbol indicates each detected event. Furthermore, the acoustic indicator will automatically be enabled temporarily, if it is not already switched on. Because the PACE 203H goes through an initializa-

tion algorithm, individual intrinsic events may or may not be detected.

Auto Sense Menu		Key No.
		1
Searching A-Sense	♥	2
Searching V-Sense	♥	3
hold...		4
		5

Table 23: Auto Sense Menu (Searching)

If the PACE 203H has found an intrinsic heart rhythm, it will display the sensed EGM amplitude as shown in Table 24.

Auto Sense Menu	Key No.
Sensed:	1
A = 2.3 mV	2
V = 8.0 mV	3
Finished (release key)	4
	5

Table 24: Auto Sense Menu (intrinsic rhythm found)

The softkey labeled *Initiate* can now be released. An appropriate sensitivity value will be automatically selected and set which will be visible in the upper display. Furthermore the sign **AUTO** will be shown in the respective section(s) of the upper display. The lower display will return to the Auto Sense Menu with the boxes checked (blinking ceases) as shown in Table 25.

Auto Sense Menu		Key No.
		1
Atrial Auto Sense	☑	2
Ventricular Auto Sense	☑	3
		4
↑_		5

Table 25: Auto Sense Menu (finished)

9.9.4.4 Notes for the Initialization of the Auto Sense function

If the user continues to press the softkey labeled *Initiate*, the PACE 203H will continue to search for intrinsic activity and find the optimal value.

If the PACE 203H detects frequencies higher than the noise frequency (273 bpm) during the Auto Sense initialization, the corresponding interference symbol ( ) is shown in the upper display. Any P or R wave value determined by the PACE 203H during interference is cleared off the display. 2 seconds after the PACE 203H determines interference with the Auto Sense function enabled, the sensitivity setting will be doubled in order to find a sensitivity level where the

heart activity is sensed without interference.

If no activity is sensed in a channel for 3 seconds, a previously determined P or R wave will be cleared off the display.

If no activity is sensed in a channel for 3 seconds, a previously determined P or R wave will be cleared off the display. Table 26 shows an example were an atrial rhythm could be found, but no ventricular rhythm.

Auto Sense Menu	Key No.
Sensed:	1
A = 2.3 mV	2
No V-Sense	3
Finished (release key)	4
	5

Table 26: Auto Sense Menu (no R-wave found)

If no intrinsic rhythm is detected in one or both channels, the respective check mark continues blinking after returning to the previous menu. The initialization request persists as shown in Table 27.

Auto Sense Menu		Key No.
		1
Atrial Auto Sense	☑	2
Ventricular Auto Sense	☑	3
Initiate. (press & hold)		4
↑_		5

Table 27: Auto Sense Menu (one channel initialization request)

The user can decide if another attempt shall be made to find an intrinsic rhythm, or if the procedure shall be terminated using the ↑_ key. In the previous example, the Auto Sense feature will then be enabled only in the atrial channel.

9.9.4.5 Re-Initialization of Auto Sense

Once activated, the Auto Sense feature can be easily re-initialized by just pressing and holding the key **PAUSE** (see 9.15). However, this is only necessary if the amplitude of the intrinsic activity has decreased so dramatically and rapidly such that the Auto Sense algorithm could not follow this change.

Warning: If frequencies higher than the noise frequency (273 bpm) are detected during the re-initialization, the corresponding interference symbol (…) will be displayed in the upper display. The sensitivity setting will remain unchanged and

the measured frequency will be displayed, because it may be a high-6frequency tachycardia. This behavior is different from Auto Sense initialization (see above), where the sensitivity value will be increased step by step in case of noise.

9.9.4.6 Deactivation of Auto Sense

The Auto Sense function can be disabled either via the Auto Menu or simply by rotating the respective (unlocked) **A-SENSE** or **V-SENSE** dial a few clicks (approx. a quarter of one revolution).

If a **SENSE** dial has been turned to deactivate Auto Sense, the transient message

Atrial Auto Sense turned off	or	Ventricular Auto Sense turned of

appears in the lower display, accompanied by a short beep. The label **AUTO** disappears from the upper display.

Using the Auto menu, the Auto Sense function is disabled by pressing the corresponding softkey. As a consequence, the corresponding check box is unchecked. The label **AUTO** disappears from the upper display.

Note: Upon a mode change (for instance VVI → AAI or DDD → VVI) that disables a channel, the Auto Sense function, enabled in this particular channel, is disabled. The Auto Sense function is not reactivated upon enabling the particular channel, because the EGM amplitudes could have changed significantly during the time the Auto Sense function was disabled.

9.10 The High-Rate / Overdrive Stimulation

The PACE 203H provides a function for atrial high-rate stimulation, also known as atrial overdrive stimulation, or rapid atrial pacing, and a function for ventricular rapid pacing. Both functions become accessible by entering the main menu via the softkey labeled *Main Menu*, and, then, by selecting either *Atrial High-Rate* or *Ventricular Rapid Pacing* via the corresponding softkey.

Table 28 shows the High-Rate Menu.

Note: Remember to press the key **Unlock/Lock** in case the PACE 203H keypad is locked. In case the lower display was turned off, it is then turned on.

High-Rate Menu	Key No.
Atrial High-Rate	1
	2
Ventricular Rapid Pacing	3
	4
↑_	5

Table 28: High-Rate Menu

9.10.1 Atrial High-Rate Standby

The Atrial High-Rate standby is accessed by pressing the softkey labeled *Atrial High-Rate* in the High-Rate Menu (Table 28). The Atrial High-Rate Standby Menu appears as shown in Table 29. The atrial high-rate stimulation is now at standby. The acoustic indicator is automatically switched on temporarily, if it is not already on.

Note: Within the Atrial High-Rate Standby Menu, the pacemaker continues to operate in the set mode.

Any previously selected atrial high-rate stimulation frequency and the corresponding beat-to-beat interval are displayed.

Note: After turning on, the PACE 203H atrial high-rate stimulation frequency is set to the default value 240 ppm if the device has been powered off using the softkey labeled *Off (no storage)*. If the device has been powered off with the softkey labeled *Stand-by (store data)* then it will restore the high rate frequency which was set before powering off.

Atrial High-Rate Standby Menu	Key No.
START (Atrium)	1
240 ppm (250 ms)	2
Use RATE Dial to change High-Rate!	3
	4
↑_	5

Table 29: Atrial High-Rate Standby Menu

The atrial high-rate stimulation frequency can be adjusted by using the **RATE** dial. This means that the **RATE** dial defaults into a **HIGH-RATE** dial for adjustment of the atrial high-rate stimulation frequency as long as the Atrial High-Rate Standby Menu is present. This is indicated by a blinking symbol **HI-** in front of the label **RATE** (together this forms **HI-RATE**) in the upper display.

The atrial high-rate stimulation frequency can be changed in 10 ppm increments between 70 ppm and 1000 ppm, as shown in Table 30.

Parameter	Adjustable Values	Unit
Atrial High-Rate	70 (10) 1000	ppm

Table 30: Range and step width (in parenthesis) for Atrial High-Rate

The PACE 203H delivers atrial high-rate stimulation impulses upon pressing and holding the softkey labeled *START*. The pacemaker switches to the A00 mode and stimulates with the set atrial high-rate stimulation frequency, showing the Atrial High-Rate Running Menu (Table 31). To return to the mode menu (Table 9 on page 28), please press the key ↑_.

Warning: There is a risk of causing ventricular tachycardia during atrial high-rate stimulation. Continuous ECG-monitoring of the patient is therefore mandatory. A defibrillator should always be available and ready to use.

Note: During atrial high-rate stimulation, the PACE 203H switches temporarily (as long as the *START (Atrium)* key is pressed) to A00 mode. To prevent confusion, the upper display remains merely unchanged and does not reflect the A00 mode (allowing the user to pre-set normal pacing parameters).

Note: Within the Atrial High-Rate Standby Menu, the pacemaker does not lock the key pad automatically.

Menu when Atrial High-Rate is running	Key No.
Running...	1
240 ppm (250 ms)	2
Use RATE Dial to change High-Rate!	3
	4
↑_	5

Table 31: Menu while Atrial High-Rate is running

After releasing the softkey labeled *START (Atrium)*, now labeled *Running...*, the PACE 203H abandons the delivery of atrial high-rate stimulation impulses, and returns to Atrial High-Rate standby. If the atrial high-rate stimulation frequency has been changed during *Atrial High-Rate running*, the basic rate prior the start of the high-rate stimulation is restored. Thus, a rate change during running overdrive stimulation is only temporary. This allows a ramp stimulation to always be started with the same rate.

The atrial high-rate mode is abandoned by pressing the softkey ↑_, which forces the PACE 203H to return to the Mode Menu (Table 9 on page 28).

After the start of an atrial high-rate stimulation, the lead surveillance in the atrial channel (see chapter 9.22.2 on page 74) is enabled. If no atrial lead is connected, the error message

Atrial lead disconnected

will consequently appear. Nevertheless, the impulse emission (with the atrial high-rate stimulation frequency) will be carried out. After releasing the softkey labeled *START (Atrium)*, the previous state of the lead surveillance will be restored.

The Pause function (see chapter 9.15 on page 62) can be used to measure the intrinsic rate of atrial tachycardia up to rates of about 700 bpm). Thus, the Pause function assists in determining the optimal atrial high-rate stimulation frequency. Please note that the atrial frequency measurement can be affected by cross-blanking after ventricular senses.

As long as the softkey labeled *START (Atrium)* is pressed, all other keys and dials are disabled.

9.10.1.1 Atrial High-Rate Stimulation with Ramp Function

The PACE 203H provides a function allowing the application of atrial high-rate stimulation with a ramp function. While the atrial high-rate stimulation is running (Atrial High-Rate Running Menu, Table 31 is shown), turning the **HIGH-RATE** dial changes the atrial high-rate stimulation rate. This feature allows the user to manually set a ramp function for atrial high-rate stimulation.

Note: The PACE 203H ignores any rotation of the **HIGH-RATE** dial beyond the defined minimum or maximum settings.

9.10.2 Ventricular Rapid Pacing Standby

The Ventricular Rapid Pacing standby is accessed by pressing the softkey labeled *Ventricular Rapid Pacing*. The Ventricular Rapid Pacing Standby Menu appears as shown in Table 32. The ventricular rapid pacing is now at standby. The acoustic indicator is automatically switched on temporarily, if it is not already on.

Note: Within the Ventricular Rapid Pacing Standby Menu, the pacemaker continues to operate in the set mode.

Any previously selected ventricular rapid pacing stimulation frequency and the corresponding beat-to-beat interval are displayed.

Note: After turning on the PACE 203H the ventricular rapid pacing stimulation frequency is set to the default value 180 ppm if the device has been powered off using the softkey labeled *Off (no storage)*. If the device has been powered off with the softkey labeled *Stand-by (store data)* then it will restore the rapid ventricular pacing frequency which was set before powering off.

Ventricular Rapid Pacing Standby Menu	Key No.
START (Ventricle)	1
180 ppm (333 ms)	2
Use RATE Dial to change Rapid Pacing Rate!	3
	4
↑_	5

Table 32: Ventricular Rapid Pacing Standby Menu

The ventricular rapid pacing stimulation frequency can be adjusted by using the **RATE** dial. This means that the **RATE** dial defaults into a **HIGH-RATE** dial for adjustment of the ventricular rapid pacing rate as long as the Ventricular Rapid Pacing Standby Menu is present. This is indicated by a blinking symbol **HI-** in front of the label **RATE** (together this forms **HI-RATE**) in the upper display.

The ventricular rapid pacing rate can be changed in 2 ppm increments between 180 ppm and 220 ppm, as shown in Table 33.

Parameter	Adjustable Values	Unit
Ventricular Rapid Pacing Rate	180 (2) 220	ppm

Table 33: Range and step width (in parenthesis) for Ventricular Rapid Pacing

The PACE 203H delivers ventricular rapid pacing stimulation impulses upon pressing and holding the softkey labeled *START (Ventricle)*. The pacemaker switches to the V00 mode and stimulates with the set ventricular rapid pacing rate, showing the Ventricular Rapid Pacing Running menu (Table 34). To return to the mode menu (Table 9 on page 28), please press the key ↑_.

Warning: There is a risk of causing ventricular tachycardia during ventricular rapid pacing-stimulation. Continuous ECG-monitoring of the patient is therefore mandatory. A defibrillator should always be available and ready to use.

Note: During ventricular rapid pacing stimulation, the PACE 203H switches temporarily (as long as the *START (Ventricle)* key is pressed) to V00 mode. To prevent confusion, the upper display remains merely unchanged and does not reflect the V00 mode (allowing the user to pre-set normal pacing parameters).

Note: Within the Ventricular Rapid Pacing Standby Menu, the pacemaker does not lock the key pad automatically

Note: For safety reasons the ventricular rapid pacing function does not offer a higher stimulation rate than would also available in normal operation.

Menu when Ventricular Rapid Pacing is Running	Key No.
Running...	1
180 ppm (333 ms)	2
Use RATE Dial to change Rapid Pacing Rate!	3
	4
↑_	5

Table 34: Menu while Ventricular Rapid Pacing Running

After releasing the softkey labeled *START (Ventricle)*, now labeled *Running…*, the PACE 203H abandons the delivery of ventricular rapid pacing stimulation impulses, and returns to Ventricular Rapid Pacing Standby. If the ventricular rapid pacing rate has been changed during *Ventricular Rapid Pacing Running*, the basic rate prior the start of the ventricular rapid pacing is restored. Thus, a rate change during running ventricular rapid pacing is only temporary. This allows a ramp stimulation to always be started with the same rate.

The ventricular rapid pacing mode is abandoned by pressing the softkey ↑_,

which forces the PACE 203H to return to the Mode Menu (Table 9 on page 28).

After the start of an ventricular rapid pacing stimulation, the lead surveillance in the corresponding channel is enabled (see chapter 9.22.2 on page 74). If no ventricular lead is connected, the error message:

Ventricular lead disconnected

will consequently appear. Nevertheless, the impulse emission (with ventricular rapid pacing rate) will be carried out. After releasing the softkey labeled *START (Ventricle)*, the previous state of the lead surveillance will be restored.

The Pause function (see chapter 9.15 on page 62) can be used to measure the intrinsic ventricular rate. Thus, the Pause function may assists in determining the optimal ventricular rapid pacing rate.

As long as the softkey labeled *START (Ventricle)* is pressed, all other keys and dials are disabled.

9.10.2.1 Ventricular Rapid Pacing with Ramp Function

The PACE 203H provides a function allowing the application of ventricular rapid pacing with a ramp function. While the ventricular rapid pacing is running (Ventricular Rapid Pacing Running Menu, Table 34 is shown), turning the **HIGH-RATE** dial changes the ventricular rapid pacing rate. This feature allows the user to manually set a ramp function for ventricular rapid pacing stimulation.

Note: The PACE 203H ignores any rotation of the **HIGH-RATE** dial beyond the defined minimum or maximum settings.

9.11 Standard Programs

The PACE 203H provides the capability of storing and recalling a user defined standard set of parameters (a so called "standard program") for each primary mode of operation (DDD, VVI, AAI, VDD). That is, four different standard programs can be stored. Alternatively, the user can reset each primary mode to the manufacturer's default settings. In addition, the initial mode and parameter settings can be configured in the Turn-on program.

To perform one of these functions, the Standard Menu must first be entered via the softkey labeled *Main Menu*, and then via the softkey labeled *Standard.* If the lower display is off, then pressing the key **Unlock**/**Lock** turns the display on. The Standard Menu appears as shown in Table 35.

Standard Menu	Key No.
Save as Turn-on	1
Save as XXX standard	2
Recall XXX standard	3
Manufacturer's-default	4
↑_	5

Table 35: Standard Menu

9.11.1 Parameters Stored in a Standard Program

The parameters stored in each of the four sets are marked with "+" in Table 36. The parameters marked with "–" are not stored in the set and will remain unchanged if a stored program is recalled.

Parameter	DDD	VVI	AAI	VDD	Unit
Basic Rate	+	+	+	+	ppm
Atrial Amplitude	+	–	+	–	V
Atrial Sensitivity (incl. Automatic state)	+	–	+	+	mV
Atrial Pulse Duration	+	–	+	–	ms
Ventricular Stimulation	+	+	–	+	–
Ventricular Amplitude	+	+	–	+	V
Ventricular Pulse Duration	+	+	–	+	ms
Ventricular Sensing	+	+	–	+	
Ventricular Sensitivity (incl. Automatic state)	+	+	–	+	mV
A-V Delay (incl. Automatic state)	+	–	–	+	ms
PVARP (incl. Automatic state)	+	–	–	+	ms
MTR (incl. Automatic state)	+	–	–	+	ppm
Atrial Trigger Option	+	–	+	–	–

Table 36: Standard Programs Set

Note: Because the sensitivity and the options are also stored, the pacing mode stored may also be one of the supplementary modes (D00, DVI, VAT, V00, A00, AAT and DDD+AT).

Warning: Because the automatic condition of the sensitivity adjustment is also stored, recalling a standard setting with Auto Sense = ON is followed by the request to search for initial sensitivity values as described in chapter 9.9.4.3. Therefore, storing a standard program with Auto Sense activated, is only recommended for experienced users.

Note: Upon the manufacturer's shipping of the PACE 203H, the user standard settings are identical with the manufacturer's defaults (see chapter 9.11.4).

9.11.2 Store Standard Programs

By pressing the softkey labeled *Save as XXX standard* in the Standard Menu (Table 35) the actual setting will become the standard for the current primary

mode (XXX stands for one of the primary modes DDD, VVI, AAI or VDD) upon answering the question Overwrite standard XXX program? With *YES* (Table 37).

Standard Saving Confirmation	Key No.
Overwrite standard XXX program?	1
	2
YES	3
NO	4
↑_	5

Table 37: Standard Saving Confirmation

After storing the user defined Standard Program, the PACE 203H abandons the Standard Menu and returns to the Mode Menu.

If the question *Overwrite standard XXX program?* If answered with “NO”, the PACE 203H returns to the (previous) Standard Menu.

Pressing the softkey ↑_ forces the PACE 203H to revert to the Mode Menu.

9.11.3 Recall Standard Programs

By pressing the softkey labeled *Recall XXX standard* in the Standard Menu (Table 35), the stored standard program for the current primary mode (XXX stands for one of the primary modes DDD, VVI, AAI or VDD) becomes the actual setting.

After pressing the softkey labeled Recall XXX standard, the PACE 203H abandons the Standard Menu and returns to the Mode Menu.

9.11.4 Recall Manufacturer’s Defaults

By pressing the softkey Manufacturer’s default in the Standard Menu (Table 35), the manufacturer’s default for the current primary mode (as shown in Table 38) becomes the actual setting.

After pressing the softkey *Manufacturer’s default*, the PACE 203H abandons the Standard Menu and returns to the Mode Menu.

Parameter	DDD	VVI	AAI	VDD	Unit
Basic Rate	72	72	72	72	ppm
Atrial Overdrive Stimulation Start Rate	240	–	240	–	ppm
Ventricular Rapid Pacing Start Rate	180	180	–	180	ppm
Atrial Amplitude	5	–	5	–	V
Atrial Sensitivity	1	–	1	0.5	mV
Atrial Pulse Duration	1	–	1	–	ms
Ventricular Amplitude	8	8	–	8	V
Ventricular Pulse Duration	0.75	0.75	–	0.75	ms
Ventricular Sensitivities	2	2	–	2	mV
A-V Delay	AUTO i.e. 180	–	–	AUTO i.e. 180	ms
PVARP	AUTO i.e. 280	–	–	AUTO i.e. 280	ms
MTR	AUTO i.e. 106	–	–	AUTO i.e. 106	ms
Automatic Sensing	OFF	OFF	OFF	OFF	–
Atrial Trigger Option	OFF	–	OFF	–	–

Table 38: Manufacturer's Default Programs

9.11.5 Changing the Turn-On Program

By pressing the softkey *Save as Turn-on* in the Standard Menu (Table 35), the actual setting will become the permanent Turn-On program when the question *Overwrite Turn-on program?* is answered with "YES" (Table 39).

Turn-on Saving Confirmation	Key No.
Overwrite Turn-on program?	1
	2
YES	3
NO	4
↑_	5

Table 39: Turn-on Saving Confirmation

After storing the user defined Turn-on Program, the PACE 203H abandons the Turn-On Menu and returns to the Mode Menu.

is answered with "NO", the PACE 203H returns to the (previous) Standard Menu.

Pressing the ↑_ key forces the PACE 203H to revert to the Mode Menu.

Note: Upon the manufacturer's shipping of the PACE 203H, the Turn-On Program parameters are set according to Table 40.

Parameter	Value	Unit
Mode	DDD	–
Basic Rate	60	ppm
Overdrive Stimulation Start Rate	240	ppm
Atrial Amplitude	5	V
Atrial Sensitivity	0.5	mV
Atrial Pulse Duration	1	ms
Ventricular Amplitude	8	V
Ventricular Pulse Duration	0.75	ms
Ventricular Sensitivity	1	mV
A-V Delay	AUTO i.e. 200	ms
PVARP	AUTO i.e. 280	ms
MTR	AUTO i.e. 100	ppm
Automatic Sensing	OFF	–
Atrial Trigger Option	OFF	–

Table 40: Manufacturer's Turn-on Program

Warning: The Manufacturer's Turn-on program is intended to provide a safe and conservative pacing therapy for the patient. A change of this program is only recommended for experienced users.

Note: Because the sensitivity and the options are also stored, the pacing mode

stored may also be one of the supplementary modes (D00, DVI, VAT, DAT, V00, A00, AAT and DDD+AT).

Note: Because the automatic state of the sensitivity adjustment is also stored, turning on a pacemaker with a Turn-on program with Auto Sense = ON is followed by the request to search for initial sensitivity values, as described in chapter 9.9.4.3. Because the patient should be provided with a therapeutic pacing program immediately after turning on the PACE 203H, storing a Turn-On Program with Auto Sense enabled is **NOT** recommended.

Note: The Turn-on Program also stores a changed Overdrive Stimulation Start Rate.

9.12 Parameters/Options Setting

The PACE 203H provides the capability of setting additional stimulation parameters and enabling or disabling options. To accomplish this, the Parameters/Options Menu must be entered via the softkey labeled *Main Menu* and, then, via the softkey labeled Parameters/Options.

If the lower display is off, then pressing the key **Unlock**/**Lock** turns the display on.

The Parameters/Options Menu appears as shown in Table 41.

At this point the corresponding softkeys for the menu setting PVARP & MTR, pulse duration, difference AVD-PVD, ARP or further options can be chosen.

Parameters/OptionsMenu	Key No.
PVARP & MTR	1
ARP & VRP	2
Pulse Duration	3
Options	4
↑_	5

Table 41: Parameters/Options Menu 1

9.12.1 Adjustment of PVARP

The post ventricular atrial refractory period (PVARP) can be adjusted by pressing the softkey *PVARP & MTR* in the Parameters/Options Menu. The PVARP& MTR Menu appears as shown in Table 42.

PVARP & MTR Menu		Key No.
PVARP	↑	1
280 ms	↓	2
MTR	↑	3
106 ppm	↓	4
↑_		5

Table 42: PVARP & MTR Menu

The PVARP can be changed with the softkey labeled ↑ or the softkey labeled ↓ in increments / decrements of 10 ms between 100 ms and 500 ms, respectively, as shown in Table 43.

The parameter change appears immediately in the second line of the lower display and will become effective with the next intervention interval.

Parameter	Manually Adjustable Values	Unit
PVARP	100 (10) 500	ms

Table 43: Manually Adjustable Values for PVARP (step width in parenthesis)

Note: Changing the PVARP value manually will also switch off the automatic setting, if it was activated (see chapter 9.9.2).

Note: The safety feature "protection against abnormal settings" (see chapter 9.22.7) prevents increasing the PVARP to a value which would not guarantee a minimum atrial sensing phase, or Wenckebach behavior. Any limitation of the PVARP setting will be indicated by a transient warning message in the lower display.

Note: The PVARP of the PACE 203H is divided in two parts: an absolute part and a relative part. In the absolute part (90 ms) no atrial events are recognized. In the relative part (the remaining) atrial events are registered, but not tracked. This algorithm prevents misinterpretation of ventricular events after premature atrial events as extrasystoles (PVCs) as described in chapter 9.22.5.

9.12.2 Adjustment of MTR

The maximum tracking rate (MTR) can be adjusted by pressing the softkey *labeled PVARP & MTR* in the Parameters/Options Menu.

The PVARP &MTR Menu appears as shown in Table 44.

PVARP & MTR Menu		Key No.
PVARP	↑	1
280 ms	↓	2
MTR	↑	3
106 ppm	↓	4
↑_		5

Table 44: PVARP & MTR Menu

The MTR can be changed with the softkey labeled ↑ or the softkey labeled ↓ in increments / decrements of 2 ppm between 80 ppm and 230 ppm, respectively, as shown in Table 45

The parameter change appears immediately in the fourth line of the lower display and will become effective with the next intervention interval.

Parameter	Manually Adjustable Values	Unit
MTR	80 (10) 230	ppm

Table 45: Manually Adjustable Values for MTR (step width in parenthesis)

Note: Changing the MTR value manually will also switch off the automatic setting, if it was activated (see chapter 9.9.3).

Note: The safety feature "protection against abnormal settings" (see chapter 9.22.7) prevents decreasing the MTR to a value smaller than the basic rate. Increasing the MTR will be limited to a value that still guarantees Wenckebach behavior. The limitation of the MTR value will be indicated by a transient warning message in the lower display.

9.12.3 Adjustment of Pulse Duration

The pulse durations can be adjusted by pressing the softkey labeled *Pulse duration* in the Parameters/Options Menu.

The Pulse Duration Menu appears as shown in Table 46.

Pulse Duration-Menu		Key No.
A	↑	1
1.00 ms	↓	2
V	↑	3
0.75 ms	↓	4
↑_		5

Table 46: Pulse Duration Menu

The pulse duration can be changed with the softkey labeled ↑ or the softkey labeled ↓ in increments / decrements of 0.05 ms between 0.05 ms and 1.50 ms, respectively, as shown in Table 47.

The parameter change appears immediately in corresponding line of the lower display and will become effective with the next intervention interval.

Parameter	Manually Adjustable Values	Unit
Atrial Pulse Duration	0.05 (0.05) 1.50	ms
Ventricular Pulse Duration	0.05 (0.05) 1.50	ms

Table 47: Manually Adjustable Values for Pulse Duration (step width in parenthesis)

9.12.4 Adjustment of Atrial (ARP) and Ventricular (VRP) Refractory Period

The atrial refractory period (ARP) and the ventricular refractory period (VRP) of this pacemaker can be changed.

By pressing the softkey labeled ARP & VRP in the Parameters/Options Menu, (Table 41 on page 51) the ARP & VRP Menu appears as shown in Table 48.

The ARP & VRP Menu can be used to change the setting for ARP and VRP.

ARP & VRP Menu		Key No.
ARP	↑	1
250 ms	↓	2
VRP	↑	3
250 ms	↓	4
↑_		5

Table 48: ARP & VRP Menu

The ARP can be changed with the softkey labeled *ARP* ↑ or the softkey labeled *ARP* ↓ in increments / decrements of 10 ms between 250 ms and 400 ms, respectively, as shown in Table 49. The manufacturer's defaults setting is 250 ms (refer to section 9.11.4 on page 48).

Parameter	Manually Adjustable Values	Unit
ARP	250 (10) 400	ms

Table 49: Manually Adjustable Values for ARP (AAI, AAT)

The VRP can be changed with the softkey labeled *VRP* ↑ or the softkey labeled *VRP* ↓ in increments / decrements of 10 ms between 250 ms and 500 ms, respectively, as shown in Table 50.

Parameter	Manually Adjustable Values	Unit
VRP	250 (10) 500	ms

Table 50: Manually Adjustable Values for VRP

The parameter changes appear immediately in the corresponding line of the lower display (see Table 48) and will become effective with the next intervention interval.

9.12.5 Setting Options

The Options Menu consists of two parts. It appears as shown in Table 51 and Table 52. By pressing the softkey *more...* one can switch between Options Menu 1 and Options Menu 2.

Options Menu 1		Key No.
Beep	☐	1
Alarms	☑	2
Atrial Trigger	☐	3
more …		4
↑_		5

Table 51: Options Menu 1

By pressing the softkey labeled *Options* in the Parameters/Options Menu, the Option Menu 1 for enabling and disabling acoustic signals (beep), alarms and atrial trigger appears, as shown in Table 51.

The user language can be set via the Options Menu 2 by pressing the softkey labeled *Language* as shown in Table 52.

The meaning of the second line in Options Menu 2 is explained in sections 9.20 (page 70) and 9.21 (page 72).

The statistic feature from the third line is explained in section 9.13 on page 58.

Options Menu 2	Key No.
Language	1
PMC ○ BPI ⊙	2
Statistics	3
more …	4
↑_	5

Table 52: Options Menu 2

9.12.5.1 Enable and Disable Acoustic Indicator

With the softkey labeled *Beep* in the Options Menu 1, the acoustic indicator can be enabled or disabled. The corresponding check box then gets checked or unchecked, respectively. If the acoustic indicator is enabled, the symbol for a loudspeaker (see Figure 7) appears in the upper display.

Figure 7: Acoustic Indicator (Symbol for a Loudspeaker)

With the acoustic indicator enabled, the delivery of a stimulus is indicated by a high-pitched tone (beep), whereas sensing of a P or R wave will be signaled by a beep of lower frequency.

Once enabled, the acoustic indicator is disabled by pressing the softkey labeled *Beep*.

The check mark disappears from the corresponding check box. The loudspeaker symbol disappears from the upper display, as well.

Upon powering off the PACE 203H, it retains the enabled / disabled status of the acoustic indicator. Thus, the enabled/disabled status of the last usage is restored again upon powering on the PACE 203H.

Upon the manufacturer's shipping of the PACE 203H, the acoustic indicator is disabled according to Table 48.

Note: The warning and error signals are not influenced whether or not the acoustic indicator is enabled or disabled. Warning and error signals are always accompanied by acoustic signals.

9.12.5.2 Enable and Disable the Alarms

With the softkey labeled *Alarms* in the Options Menu, the lead surveillance feature (see chapter 9.22.2) and the protection against abnormal settings (see chapter 9.22.7) can be enabled or disabled.

Warning: Alarms should only be disabled in a controlled environment, specifically, where medical professionals continuously monitor the patient.

Upon turning on the PACE 203H, the alarms are always enabled.

With alarms enabled, pressing the softkey labeled *Alarms* causes the check mark to disappear from the corresponding check box. In the upper display, the crossed bell symbol (see Figure 8) is shown.

Figure 8: Alarms Off (Crossed Bell) Symbol

To reactivate the lead surveillance feature and the protection against abnormal settings the Alarms key must be pressed again. This causes the check mark to appear in the corresponding check box, and the crossed bell symbol in the upper display disappears.

Note: If previously disabled Alarms are enabled, the PACE 203H will solve possible conflicts caused by abnormal settings using its Automatic setting feature. The fact that a parameter has been adapted according (see chapter 9.22.7 and 9.9).

9.12.5.3 Enable and Disable Atrial Trigger Function

When the atrial trigger function is enabled, the PACE 203H delivers an atrial stimulus immediately after an atrial sensing within the atrial sensing phase.

With the softkey labeled *Atrial Trigger* in the Options Menu, the atrial trigger function can be enabled or disabled. In case the atrial trigger function is enabled, the corresponding check box is checked. Furthermore, the PACE 203H indicates the label **A-TRIG** in the atrial stimulation section of the upper display.

Note: The atrial trigger function is available in the primary modes AAI and DDD.

To turn the atrial trigger function off, the softkey labeled *Atrial Trigger* must be pressed again. The check mark disappears from the corresponding check box,

and the label **A-TRIG** disappears from the upper display as well.

Atrial Trigger is also disabled when the primary mode is changed to VVI or VDD, because these modes do not provide atrial stimulation. Atrial Trigger must be activated again after changing back to the primary modes AAI or DDD.

Note: Atrial Trigger cannot be used together with Atrial Auto Sense, because the triggered stimulation prevents proper measurement of the intrinsic atrial activation. (see also 9.9.4).

Note: A sensed atrial event in the relative PVARP (see chapter 9.12.1) is never followed by a (triggered) atrial stimulation – even if atrial trigger is enabled – because it may be a ventricular echo.

9.12.5.4 Setting the User Language

By pressing the softkey labeled *Language* in the Options Menu 2, the Language Menu appears as shown in Table 53. The activated user language is marked. By pressing the corresponding key the language can be selected. The softkey labeled *more...* toggles through the different language menus.

Language Menu		Key No.
English	⊙	1
Deutsch	○	2
Français	○	3
more...		4
↑_		5

Table 53: Language Menu

The manufacturer's language setting default is English.

9.12.5.5 Setting CTRL.OUT Interface

By pressing the softkey labeled *PMC / BPI* in the Options Menu 2, the CTRL.OUT port is set to either communicate with the Pacemaker Clinic (PMC; a feature of AESCULON™ and ICON™ Electrical Cardiometry™ monitors) or with the optional BPI 202 intra-aortic balloon pump (IABP) interface.

9.13 Statistics

By pressing the softkey labeled *Statistics* in the Options Menu 2 (see Table 52 on page 55), the user can review statistical data obtained by the PACE 203H presented in four different statistics screens.

Please refer to Table 54: Statistical Parameters and to Figure 9.

Page	Parameter	Explanation
Page I	Statistics Runtime (Runtime)	Time since last reset of statistics counters (power-on or manual reset)
	Pacer Settings (Unchanged / Changed)	Indicates if during the Runtime any of the pacemaker settings (mode or parameter) were changed or not.
	Total Cycles (Cycles)	Number of cardiac cycles counted during Runtime
Page II	Atrial Paced Cycles (AP)	Number of atrial paced cycles counted during Runtime, and the percentage with respect to the Total Cycles
	Ventricular Paced Cycles (VP)	Number of ventricular paced cycles counted during Runtime, and the percentage with respect to the Total Cycles
	Atrial Sensed Cycles (AS)	Number of atrial sensed cycles counted during Runtime, and the percentage with respect to the Total Cycles
Page III	Ventricular Sensed Cycles (VS)	Number of ventricular sensed cycles counted during Runtime, and the percentage with respect to the Total Cycles
	Longest Series AP (maxAP)	Largest series of consecutive atrial paced cycles during Runtime, and the percentage with respect to the Total Cycles
	Longest Series VP (maxVP)	Largest series of consecutive ventricular paced cycles during Runtime, and the percentage with respect to the Total Cycles
Page IV	Cycles with Extrasystoles (PVC)	Number of premature ventricular contractions (PVC) during runtime, and the percentage with respect to the Total Cycles
	Artifacted Cycles (XC)	Number of distorted cycles during runtime, and the percentage with respect to the Total Cycles. These are for example cycles with disconnected or shorted pacing leads or cycles with distortions from noise.

Table 54: Statistical Parameters

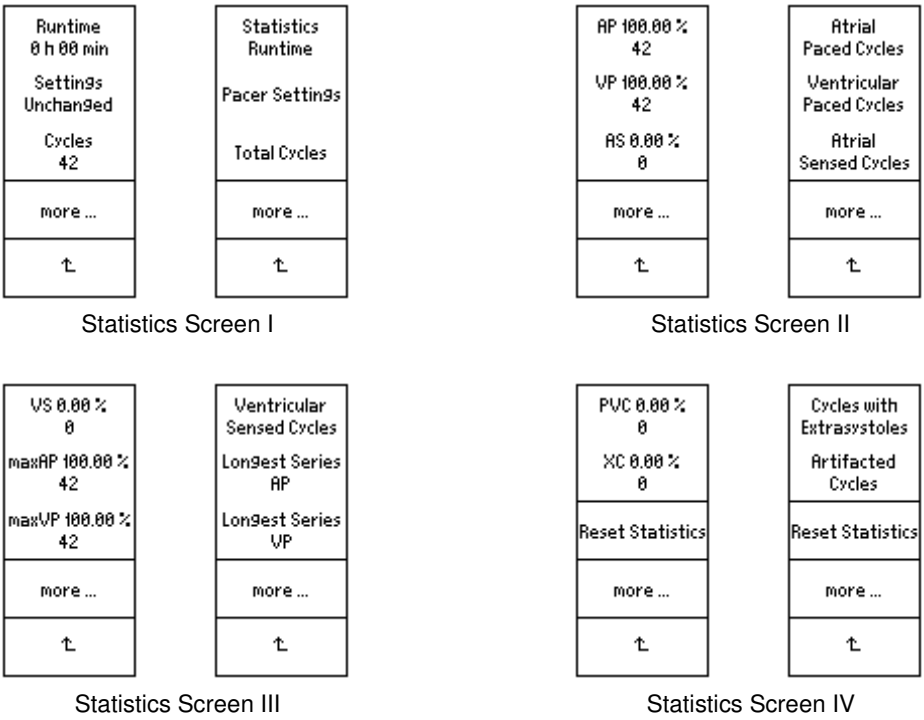


Figure 9: Displays of Statistics (automatically alternating)

Repeated pressing of the softkey labeled *more ...* toggles between the four different statistics screens I - IV, see Figure 9. The content of each statistics screen automatically alternates between the display of headers and their corresponding measurements.

The softkey labeled *Reset Statistics* provided exclusively in statistics screen IV allows a manual reset of Runtime and thus all event counters of the statistics.

Upon turning the device on, the Runtime and all statistics event counters are reset. The Runtime and the event counters are not reset if the device was put into stand-by [with *Stand-by (store data)*] and then activated again. Refer to section 9.5 on page 24 for turning off with Stand-by (store data).

Note: It is theoretically possible that some percent values in the statistics are larger than 100%, for example if there would be more than one extrasystole per cycle.

9.14 Emergency Stimulation

In case heart stimulation becomes ineffective with the set parameters in place, the PACE 203H provides an emergency stimulation program. This emergency program can be quickly and easily activated from all operational states by pressing the key **EMERGENCY**.

The PACE 203H defaults immediately to the emergency stimulation program with the parameter shown in

Emergency Stimulation Program	
Operation Mode:	V00 (A00)
Rate:	80 ppm
Amplitude (Atrium):	12 V or set value if higher
Amplitude (Ventricle):	12 V or set value if higher
Pulse Duration (Atrium):	1.00 ms or set value if higher if longer
Puls Duration (Ventricle):	0.75 ms or set value if higher if longer

Table 55.

Note: In case the PACE 203H is locked, it must be unlocked first by pressing the key **Unlock**/**Lock**.

Warning: If the device is operating in an atrial mode (AAI, AAT, A00), it defaults first to the V00 mode with the above mentioned values upon pressing the emergency key. However, if the lead surveillance determines that no ventricular lead is connected, the device switches to A00 mode.

Note: By pressing the emergency key, the PACE 203H irrevocably abandons the last parameter setting.

Emergency Stimulation Program	
Operation Mode:	V00 (A00)
Rate:	80 ppm
Amplitude (Atrium):	12 V or set value if higher
Amplitude (Ventricle):	12 V or set value if higher
Pulse Duration (Atrium):	1.00 ms or set value if higher if longer
Puls Duration (Ventricle):	0.75 ms or set value if higher if longer

Table 55: Emergency Stimulation

9.15 Pause Function

The PACE 203H allows the user to temporarily interrupt the current stimulation therapy in order to monitor the patient's intrinsic cardiac activity. This function, also referred to as PAUSE function, is activated by pressing and holding the key labeled **Pause**.

The pause function is implemented as the pacing mode 0D0 (see also chapter 9.6.10).

In case any intrinsic atrial or ventricular cardiac activity is sensed,

- the atrial rate measured in beats per minute [bpm], the corresponding PP interval [ms], and the P-wave amplitude [mV],
- the ventricular rate measured in beats per minute [bpm], the corresponding RR interval [ms] and the R-wave amplitude [mV], and
- the atrio-ventricular interval (AVI) measured in [ms]

are shown on the lower display as shown in Table 56. The parameter values are displayed after the second intrinsic sensed event. These events are detected up to frequencies of about 700 bpm.

If no cardiac activity can be sensed, or the sensitivity is set to a value much smaller or much larger than the actual P- or R-wave amplitude, the PACE 203H will change the sensitivity temporarily. The PACE 203H will attempt to find intrinsic heart activity and to measure the amplitudes optimally. When the Auto Sense function is deactivated, this change of sensitivity thresholds is only temporary. Thus, after releasing the key labeled **Pause**, the previous sensitivity threshold is restored. When the Auto Sense function is activated in one or in both channels, the changed sensitivity setting will be taken as new start value for the Auto Sense algorithm (see 9.9.4). Thus, the Auto Sense function is reinitialized with the determined sensitivity threshold.

The display is shown as long as the key labeled **Pause** is pressed, plus for approximately an additional second after releasing the key.

The acoustic indicator will automatically be enabled temporarily, if not already enabled.

Pause Menu	
Sensed:	
A	50 bpm (1200 ms) 2.3 mV
V	50 bpm (1200 ms) 8.0 mV
AVI	90 ms

Table 56: Pause Menu.
(with example values)

The pause function is activated for up to 10 seconds. Subsequently, the PACE 203H resumes pacing, independent if the user continues to hold the key labeled **Pause**.

Warning: Because pacing is interrupted, the user must be aware that the patient receives no stimulation therapy and support by the pacemaker as long as the key labeled **Pause** is pressed.

The PAUSE function is always operational, except during application of atrial overdrive stimulation. It does deploy, however, during High-Rate standby and can be used to measure the frequency of the atrial tachycardia, which assists in finding the optimal overdrive stimulation rate.

The determination of the intrinsic atrial rate can be influenced by the cross blanking after ventricular sensing. Thus, sensing of atrial activations can get "lost" due to the cross blanking, which may result in a rate determination being of too low, or unstable. Thus, if a precise measurement of the atrial frequency is desired, the ventricular lead must be disconnected.

If frequencies higher than the noise frequency (273 bpm) are detected while the key labeled **Pause** is pressed, the corresponding interference symbol (Figure 13) is displayed in the upper display. The measured frequency is displayed, nevertheless, because it may be a high-frequency tachycardia. Accordingly, for the same reason, the setting of the sensitivity threshold remains unchanged (unlike during initialization of the Auto Sense function).

When no intrinsic activity is sensed in any channel for 3 seconds while the key labeled **Pause** is pressed, any measured values already displayed are erased.

Note: As long as the key labeled **Pause** is pressed, all other keys and dials are disabled.

9.16 Connecting the Leads to the PACE 203H

9.16.1 Lead Types

For temporary stimulation of the heart with the PACE 203H, temporary transvenous leads or permanent leads, regardless of whether they are of bipolar or unipolar configuration, can be used. The use of myocardial leads (up to 6 electrodes) and VDD single pass leads is also permissible.

Temporary, transvenous pacing leads: These leads are advanced into the heart via a vein and are connected to the PACE 203H either directly or by means of an extension cable.

Heart wires (myocardial pacing leads) Heart wires (myocardial leads) are affixed to the heart during open heart surgery, when it is expected that the patient may need stimulation for a limited period of time after surgery. The heart wires are connected to the PACE 203H by means of an extension cable.

Permanent pacing leads: Prior to implantation of a permanent pacemaker, or during a pacemaker change, stimulation may be properly maintained with the assistance of the PACE 203H. The permanent lead is connected to the PACE 203H either directly or by means of an extension cable.

Warning: All lead systems must be connected to type **CF** devices only, because of the danger of current being diverted to the heart. Devices that are connected to a mains supply pose increased danger for current diversions to the heart.

For exact specifications of leads and patient cables, please refer to our product catalog.

9.16.1.1 Lead Connection Terminals

At the top of the pacemaker are protected terminals (collets) located for plugs with a diameter of 0.9 mm to 2.0 mm. Viewing the display face of the PACE 203H, the atrial connections are located to the left and the ventricular connections to the right (see Figure 1). Viewing the top of the PACE 203H, as shown in Figure 10, the ventricular connections are located to the left and the atrial connections to the right.

The indifferent terminals (+) are colored red, while the different terminals (–) are colored black.

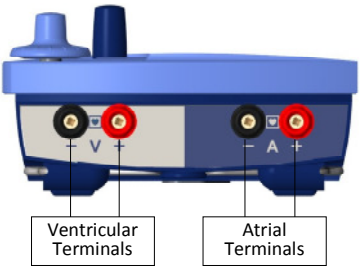


Figure 10: Lead Connection Terminals

9.16.2 Connection Configurations

Various connection configurations exist, depending on the leads used. One may choose between bipolar leads or unipolar leads with indifferent electrode.

Bipolar: When using a bipolar, transvenous stimulation lead, the distal pole of the lead is connected to the different

(–, black) terminal of the corresponding channel on the PACE 203H. The proximal pole is then connected to the indifferent (+, red) terminal.

When using heart wires, the connection is arbitrary, since both electrodes are affixed in the myocardium. The connection may be selected to obtain the best sensing and stimulation parameters.

When a stimulus is delivered, the current flows from the negative to the positive electrode, and causes a myocardial depolarization and in turn leads to a heart muscle contraction.

Unipolar: When using a unipolar lead, it is connected to the different (–, black) terminal of the corresponding channel of the PACE 203H. In order to close the circuit and allow a stimulus, an indifferent electrode must be connected to the indifferent (+, red) terminal of the corresponding channel of the PACE 203H. This electrode must have a large surface and must be attached subcutaneously.

If unipolar stimulation is given in the atrium as well as in the ventricles, one indifferent electrode is sufficient. The indifferent terminals of all channels can be connected to each other.

Warning: The unipolar configuration is more susceptible to external noise, as compared to the bipolar configuration.

9.16.3 Connecting the Leads

The PACE 203H must be turned off while the stimulation leads are connected to it.

Warning: While the leads are being inserted into the patient, and the PACE 203H is connected, continuous ECG monitoring is mandatory. For emergency situations, a defibrillator must always be in a ready-to-use state. The user must ensure that all devices in the vicinity of the patient are properly grounded.

Warning: Before handling the pacemaker, the patient cable, or the indwelling stimulation lead, the electrostatic potential between user and patient must be equalized.

The stimulation leads provide a direct, low-resistance current path to the heart. Therefore, it is absolutely mandatory that the connector plug is not touched with bare hands or can come in contact with electrically conductive or wet surfaces. All possible static electricity sources must be kept away from the stimulation system.

The user must follow the steps described below when connecting a stimulation lead to the PACE 203H:

1. Turn off the PACE 203H. Open the collets (see Figure 10)
2. If a patient cable is used, this cable must be connected first to the PACE 203H, before the stimulation lead is connected to the patient cable. Connect the ventricular pacing leads, or the corresponding extension cable, to the ventricular output terminals of

the PACE 203H. Connect the atrial pacing leads or the corresponding extension cable, to the atrial output terminals of the PACE 203H. Make sure the polarity is correct.

3. Secure the connections by manually turning the collets clockwise.
4. If extension cables are used, connect the leads to the extension cables.
5. Turn on the PACE 203H and set the desired pacing mode.
6. Determine the sensitivity threshold (see chapter 9.17).
7. Determine the cardiac capture threshold (see chapter 9.18).
8. Control the proper functioning of the PACE 203H with the assistance of an ECG monitor or recorder.

9.17 Determining the Sensitivity Threshold

Determining the sensitivity threshold can be accomplished by using the Auto Sense function (see chapter 9.9.4) or manually. Both methods require that the patient has intrinsic heart activity.

For manual determination of the sensitivity threshold, the patient must have heart activity with a rate that is hemodynamically tolerated over a longer period of time (a few minutes).

The manual determination of the sensitivity threshold is performed as follows:

1. Set the stimulation amplitude (in dual-chamber mode: both channels) to the smallest value so that any asynchronous stimulation, which occurs during the procedure, remains ineffective.
2. Set the basic rate 10 ppm below the patient's intrinsic rate.
3. If the PACE 203H is operating in a dual chamber mode, the A-V delay must be set longer than the patient's intrinsic A-V interval.
4. In case the pacemaker already senses intrinsic heart activity in the atrial or ventricular channel, set the sensitivity at a low level (i.e. raise the sensitivity value), such that the PACE 203H will not sense intrinsic events in the atrium and ventricle, respectively. Eventually, the PACE 203H operates in asynchronous pacing mode.
5. Raise the sensitivity (i.e. lower the sensitivity value) again until stimulation is inhibited. This sensitivity set equals the sensitivity threshold. In order to create a 'safety cushion', the sensitivity must be raised further. The set value should be a 1/2 to 1/3 of the sensitivity threshold value.
6. In case a dual chamber mode is chosen, the procedure must be repeated for the other channel.

Warning: An unnecessarily high sensitivity (i.e. smaller sensitivity value) increases the probability that the proper pacemaker function will be affected by external interference, and the pacemaker will switch to asynchronous stimulation (see also chapter 9.22.3).

Note: When setting the sensitivity threshold, it is very helpful to turn on the acoustic signal of the PACE 203H, because it emits a different pitched tone for stimulation and for sensing (see chapter 9.12.5.1).

9.18 Determining the Cardiac Capture Threshold

Warning: If the patient has a sufficient intrinsic heart rate, the determination of the sensitivity threshold must be carried out before the cardiac capture threshold can be determined. This is done in order to make certain that no asynchronous superimposition of intrinsic rhythm and stimulation occurs.

To determine the cardiac capture threshold, the following steps should be taken:

1. Set the basic rate at least 10 ppm above the patient's own rate. If the PACE 203H is already effectively stimulating, lower the stimulation amplitude, until the stimulus is no longer effective.
2. In case the PACE 203H is operating in a dual chamber mode, the A-V delay must be set shorter than the patient's intrinsic A-V interval.
3. Raise the stimulation amplitude slowly until the stimulus is effective again. The amplitude set equals the cardiac capture threshold.
4. In order to create a 'safety cushion', the stimulation amplitude must be raised further. The set value should be from two to three times the cardiac capture threshold.
5. In case a dual-chamber mode is chosen, the procedure must be repeated in the other channel.

Warning: If the PACE 203H is to be used for a longer period of time on a patient, the stimulation threshold should be checked from time to time (the first time after a few hours, then daily), because an increase in the capture threshold can occur.

9.19 AC Power Supply (Option)

Option not available in USA and Japan.

Although operation of the PACE 203H always requires a 9 V battery with sufficient charge, a medical grade AC power supply (PACE 203H accessory) can be used. While the PACE 203H is powered by the AC power supply, the 9 V battery inside the PACE 203H is not discharged. It is for safety reasons that the battery must stay inside the PACE 203H during AC operation.

The PACE 203H indicates AC operation with a green LED labeled **Mains** between the keys **Off** and **On**.

For connecting the PACE 203H to AC power, please adhere to the following instructions:

1. Turn off the PACE 203H.
2. Lift the cap that protects the terminal **CTRL. OUT** (see Figure 2).
3. Insert the connector of the AC Power Supply into the terminal **CTRL. OUT**. Secure the connection by manually turning the collets clockwise.
4. Insert the wall power supply into a mains socket.
5. Control the proper lighting of the green **Mains** LED.
6. Turn on the PACE 203H in the usual way.

Warning: If the green LED **Mains** does not light, the PACE 203H operates battery powered with the specified battery lifespan.

9.20 Controlling an Intra-Aortic Balloon Pump (Option)

Option not available in USA and Japan.

In combination with the optional BPI 202 Balloon Pump Interface, the PACE 203H can control the triggering of an intra-aortic balloon pump (IABP). The BPI 202 obtains a signal from the PACE 203H indicating a either a ventricular intrinsic depolarization or a stimulus and provides a corresponding signal to the IABP which resembles a surface QRS complex.

The PACE 203H utilizes the intracardiac electrogram obtained from the ventricular channel. The ventricular signal is processed in such a way that its characteristics (shape, impulse amplitude, base width) are similar to a signal obtained from surface electrodes.

Setup: Connect the BPI 202 and PACE 203H via the **CTRL.OUT** terminal of the PACE 203H (see Figure 1 and Figure 2). Attach the clips of the 3 leads provided by the IABP which usually are attached to 3 surface ECG electrodes to the 3 pins provided at the front of the BPI 202.

The PACE 203H accomplishes the synchronization of the IABP with the heart activity in both intrinsic and paced ventricular events by application of a differential timing:

Intrinsic Event: Upon sensing of an R wave, the PACE 203H provides a control signal, whose processed 'R wave' is delayed by approximately 5 ms, assuming that the amplitude of the R wave measured is twice the value of the sensitivity set.

Paced Event: Upon delivery of a ventricular stimulus, the PACE 203H provides a control signal, whose processed 'R wave' is delayed by approximately 35 ms, accounting for the latency period, that is, the time between actual delivery of the stimulus and the occurrence of ventricular depolarization.

Please see the instruction manual for the IABP interface device for further information.

Warning: Because the ventricular intracardiac electrogram is processed to control the IABP, the output at the terminal CTRL OUT is only enabled if a pacing mode with sensing and / or stimulation in the ventricle is chosen. The output at the terminal is disabled any time the PACE 203H operates in a pacing modes using atrial sensing and / or pacing (AAI, A00, AAT).

Enable the balloon pump interface communication by selecting the radio button assigned to BPI (manufacturer's default) in the Options Menu 2 (Table 57). Pressing the PMC/BPI softkey in the will toggle between selection of the radio button assigned to PMC (for *Pacemaker Clinic*™, a program view of the AESCULON®) and the radio button assigned to BPI (for *Balloon Pump Interface*). Balloon pump interface communication is default.

Options Menu 2	Key No.
Language	1
PMC ○ BPI ⊙	2
	3
more …	4
↑_	5

Table 57: Options Menu 2
(BPI enabled)

Note: The Terminal **CTRL.** is protected by a cap which will prevent pollution. This cap should be in place, when the CTRL OUT socket is not used.

9.21 Interfacing with Electrical Cardiometry™ Monitors (Option)

As an option, the PACE 203H interfaces with the Electrical Cardiometry™ (EC™) monitors (AESCULON™, ICON™) offered by Cardiotronic (La Jolla, CA, USA) and Osypka Medical (Berlin, Germany). These monitors can synchronize with the PACE 203H and record the pacemaker settings with the corresponding results of the hemodynamic measurements.

The PACE 203H interface to EC™ monitors is enabled by selecting the radio button assigned to PMC in the Options Menu 2 (Table 57).

Pressing the PMC/BPI softkey in the Options Menu 2 (Table 57) will toggle between the radio button assigned to PMC (for *Pacemaker Clinic*™, an EC™ monitor feature) and the radio button assigned to BPI (for *Balloon Pump Interface*).

Options Menu 2	Key No.
Language	1
PMC ⊙ BPI ○	2
	3
more …	4
↑_	5

Table 58: Options Menu 2 (PMC enabled)

The communication between the PACE 203H and the EC™ monitor is established via a custom interface cable connected at one end to the **CTRL.OUT** terminal of the PACE 203H and at the other end to the EC™ monitor. Upon successful communication, the PACE 203H parameter settings are transmitted to the EC™ monitor, and both PACE 203H and the EC™ monitor are synchronized regarding timely occurrences of atrial and ventricular stimulation.

The combination of the pacemaker and the EC™ monitor provides a helpful tool for determining the hemodynamically optimal pacing parameters. The user utilizes the EC™ monitor feature *Pacemaker Clinic™ (PMC)* to define a range for the atrio-ventricular (AV) delay, a step width for stepping through the aforementioned range and a waiting period applied between a change of the AV delay and a period of hemodynamic measurements. Upon a key stroke, the PACE 203H automatically applies the

various pacing parameter permutations for a limited time one after the other, while the obtaining and recording the corresponding hemodynamic measurements. At the end of this ‘scan’, the EC™ monitor presents the results in a matrix and suggests the optimal pacing parameter permutation, which can be accepted by the user, or ignored. Please refer to the instructions for use of the AESCULON™ or ICON™ monitor for more detailed information.

9.22 Internal Surveillance and Safety Features

9.22.1 Battery Surveillance

The PACE 203H is powered by a standard 9 V battery.

The PACE 203H continuously monitors the battery voltage. The battery symbol (see Figure 11), located in the upper display, continuously indicates the remaining battery voltage. The time-to-change-battery level is reached when only one segment (the rightmost triangular one) remains and is blinking. Additionally, the warning message

Change battery!

will appear approximately every 10 min in the lower display, accompanied by an acoustic warning signal.

Note: The text message *Change battery!* disappears only upon the user pressing the key **Unlock**/**Lock**.

Figure 11: Battery Symbol

If the time-to-change-battery warning is disregarded, and the voltage falls below a critical value, then the empty battery symbol blinks, requesting an immediate change of the battery (see chapter 11.2). This action is accompanied by the warning message

Hurry up! Change battery!

and the acoustic warning signals every 2 minutes.

The lifespan of the battery depends on the set stimulation parameters. In chapter “Technical Data” on page 101 the lifespan for 100% stimulation in two usual modes (DDD, VVI) are given for alkaline and lithium batteries.

During a battery change, the PACE 203H is capable of providing continuous operation for at least 30 seconds.

Warning: In order to provide continuous operation of the pacemaker during battery changes, it is recommended that the battery will be replaced before being completely drained (see also chapter 11.2).

If the PACE 203H is switched off, or to the stand-by state after the first request to change the battery has appeared, the battery must be replaced before the pacemaker is turned on again. The battery can be changed without losing the stored settings.

The battery surveillance cannot be turned off with the Alarms on/off option (see chapter 9.12.5.2).

9.22.2 Lead Surveillance

In order to prevent system malfunctions (Exit-Block), the PACE 203H checks, during each delivery of a stimulus, whether an interruption or a short circuit of the pacing system has occurred.

Warning: The lead surveillance is enabled only if the pacing amplitude is set greater than or equal to 2.0 V and if the pulse duration is set to a value greater than or equal to 0.15 ms.

9.22.2.1 Short Circuit in Pacing System

A short circuit in the pacing system can occur, for example, because of defective insulation. An interruption of the stimulation system can be caused by lead or cable breakage, or an incorrectly made connection.

A short circuit will be indicated by the warning messages *Atrial output short* or V*entricular output short* (see chapter 9.22.9) located in the lower display. Each warning message will also be accompanied by an acoustic warning signal. Only pressing the key **Unlock**/**Lock** will discard the warning messages for a few seconds, but will reappear if the failure persists.

9.22.2.2 Interruption in Pacing System

In case of an interruption of the stimulation circuit – which is defined as 3 successive stimulations not properly carried out – the open lead symbol (see Figure 12) will be shown in the upper display, with respect to the corresponding atrial and/or ventricular channel.

Figure 12: Open Lead Symbol

Additionally, the PACE 203H performs lead surveillance with an intelligent lead-breakage warning function, which operates independently in the atrial and ventricular channels. The PACE 203H enables this function in a channel automatically upon recognition that a lead is connected. According to the definition of the function, a lead is connected upon three sensed or paced events. In case an atrial or ventricular lead, or any part of the circuit, fractures (accidentally or on purpose, identified by three failed deliveries of pacing stimuli), the open lead symbol.

In case an atrial or ventricular lead, or any part of the circuit, fractures (accidentally or on purpose, identified by three failed deliveries of pacing stimuli), the open lead symbol (see Figure 12) appears in the respective section of the upper display, accompanied with an acoustic warning signal. The warning signal is repeated as long as the interruption persists. In addition, the warning messages *Atrial lead disconnected* or *Ventricular lead disconnected*. appear in the lower display (only if the lower display is switched on). Once the problem for the malfunction is resolved, the warning message disappears automatically, and the acoustic warning signal ceases.

The user can confirm the error message by pressing the key **Unlock**/**Lock**. Confirmation causes the warning message to disappear and the acoustic signal to cease, despite the fact, for example, that the lead remains disconnected. In this case, the PACE 203H ceases the lead-breakage warning message upon the user's confirmation, but continues to display the open lead symbol if the malfunction remains present.

If the disconnection is detected when the lower display is switched off, only the acoustic signal is enabled. A first press of the key **Unlock**/**Lock** switches on the lower display and the backlight, and unlocks the device. Then, the warning message is displayed. A second press on the key **Unlock**/**Lock** confirms the error message.

If the disconnection is detected when the lower display is switched on, but the device is locked, a first press of the key **Unlock**/**Lock** switches the backlight on, and unlocks the device. The user confirms the warning message with a second press of the key **Unlock**/**Lock**.

Once the leads are connected and functioning appropriately, the lead-breakage warning function is enabled automatically after three sensed or paced events.

Note: As long as the stimulation amplitude is set to less than 2.0 V, or the pulse duration is set less than 0.15 ms, the lead-breakage surveillance remains in the previously held status (enabled or disabled).

When the PACE 203H resumes operation from the stand-by mode, the lead-breakage surveillance is always activated. The PACE 203H assumes that the pacemaker is already connected to the pacing leads and thus, to the patient. In any other case of beginning operation, the PACE 203H first disables the lead-breakage surveillance. Thus, the user is able to set up the patient without being bothered by lead-breakage warnings, while the pacemaker is not connected to the pacing leads. However, upon proper connection of the PACE 203H to the pacing leads and, thus, the patient, the PACE 203H enables lead-breakage surveillance after three successfully sensed or paced events.

Note: The lead surveillance can be turned off using the Alarms on/off option (see Chapter 9.12.5.2). However, it is not recommended to disable the lead surveillance function.

Warning: The lead surveillance function should only be disabled if a medical professional continuously monitors the patient.

9.22.3 Interference and Mode Switching

The PACE 203H is designed for optimal sensing characteristics and filtering suppression of possible noise and interference of frequencies beyond the range of intrinsic and paced frequencies. However, there are types of interference whose frequencies hardly differ from those of intracardiac signals (for example, noise from mains supply and strong muscle potentials), and are of such magnitude that complete suppression cannot be achieved.

As a consequence, the PACE 203H implements an algorithm, which decides, by means of a rate analysis of the observed signal, whether the intrinsic events or interference is sensed:

Signals with a frequency below 273 bpm (about 4.5 Hz) will be judged as intrinsic heart signals and lead to an inhibition (or, according to the pacing mode, to a triggering) of stimulation.

Signals with a frequency above 273 bpm (about 4.5 Hz) will be judged as interference and force the PACE 203H to an asynchronous stimulation.

If the PACE 203H recognizes interference in a channel, the basic rate will be increased by 10 ppm, but not above the MTR (only in the case the MTR is applicable, and the MTR set to a value less than 10 ppm above the basic rate) and not above 220 ppm. The PACE 203H displays the symbol for interference (see

Figure 13) in the upper display (atrium and/or ventricle).

Figure 13: Symbol for Interference

Additionally, the pacemaker changes to the pacing mode due to interference. Table 59 shows the corresponding reaction.

	The pacemaker will switch to the following mode during	
Basic Mode	**Interference in Ventricular Channel**	**Interference in Atrial Channel**
DDD	D00	DVI
D00	No change	No change
VVI	V00	No change
V00	No change	No change
AAI	No change	A00
A00	No change	No change
VDD	V00	VVI

Table 59: Mode Switching Due to Interference

Note: Interference is not recognized (and indicated)

If the sensitivity of the corresponding channel is set to infinite ("–.–"), or

If the corresponding channel is refractory because sensing is turned off in all these cases.

9.22.4 Crosstalk and Ventricular Safety Pacing

In dual-chamber pacing modes, an atrial stimulus could be sensed on the ventricular channel, and inhibit ventricular stimulation. This is known as crosstalk, or A-V crosstalk. In a pacemaker-dependent patient, inhibition of ventricular output by crosstalk results in asystole.

For a better understanding how the PACE 203H prevents, or operates in the presence of crosstalk, the A-V delay should be considered as an interval with three periods: The ventricular blanking period, the ventricular triggering period, also known as the crosstalk sensing window, and the remaining period of the A-V delay, in which a sensed event inhibits the ventricular output. This remaining period may be not extant if the sum of ventricular blanking period and crosstalk sensing equals the A-V delay.

9.22.4.1 Ventricular Blanking Period

To prevent crosstalk, the PACE 203H initiates, after an atrial stimulus, a brief ventricular blanking period. As a consequence, any possible crosstalk from the atrial pacing stimulus is masked, or blanked, with respect to the ventricular sensing circuitry.

The blanking period is of short duration because it is important for the ventricular sensing circuit to be returned to the “alert” state relatively early during the A-V delay so that intrinsic ventricular activity can inhibit the ventricular output.

9.22.4.2 Crosstalk Sensing Window and Ventricular Safety Pacing

The crosstalk sensing window follows the ventricular blanking period. From

then on, the PACE 203H cannot differentiate crosstalk from intrinsic ventricular activity.

To prevent ventricular systole, the PACE 203H delivers a ventricular stimulus if either crosstalk or intrinsic ventricular activity is sensed within 40 ms after the termination of the blanking period. This interval of 40 ms is referred to as the crosstalk sensing window, and the ventricular response to as ventricular safety pacing. This ventricular pacing stimulus is delivered early, that is, 100 ms after the atrial event. This corresponds to an abbreviated A-V delay of 100 ms.

If the signal sensed is indeed crosstalk, the paced ventricular stimulus at the abbreviated A-V delay prevents ventricular asystole.

If, on the other hand, intrinsic ventricular activity occurs during this 40 ms window, the safety mechanism results in delivery of a ventricular pacing stimulus within, or immediately after, the intrinsic beat. This delivery is safe because the ventricle is refractory. Consequently, no depolarization results from the ventricular stimulus. Furthermore, the stimulus is too early to coincide with ventricular repolarization or a vulnerable period.

Crosstalk window and safety pacing are designed to supplement the ventricular blanking function to ensure that crosstalk inhibition will not occur.

The PACE 203H indicates ventricular safety pacing after A-V crosstalk through a short time interval between the blinking of the LEDs corresponding to ventricular sensing and pacing, respectively.

9.22.5 Premature Ventricular Contraction (PVC)

The PACE 203H assumes an extrasystole, or premature ventricular contraction (PVC), if it detects two ventricular events without an atrial event in between. The detection of a PVC is indicated in the ventricular section of the upper display by the symbol for an extrasystole (see Figure 14).

Figure 14: Symbol for Extrasystole (Premature Ventricular Contraction, PVC)

For patients with retrograde conduction, the sensing of a ventricular event, conducted retrograde to the atrium, can lead to pacemaker mediated tachycardia.

Note: Pacemaker mediated tachycardia has been defined as a reentry arrhythmia in which the dual-chamber pacemaker acts as the antegrade limb of the tachycardia and the natural pathway acts as the retrograde limb [2] [3].

The PACE 203H prevents pacemaker mediated tachycardia by implementation of a specific PVC algorithm. The re-

[2] Furman S, Fisher JD. Endless loop tachycardia in an AV universal (DDD) pacemaker. Pacing Clin Electrophysiol 1982; 5: 486-489.

[3] Den Dulk K, Lindemans FW, Bar FW, Wellens HJ. Pacemaker related tachycardias. Pacing Clin Electrophysiol 1982; 5: 476-485.

sponse is different in case of isolated PVC or the initial PVC of a series, and subsequent PVCs.

9.22.5.1 Isolated PVC, or Initial PVC

After detection of a PVC, the PVARP is extended to 500 ms. Therefore any sensed intrinsic atrial events are not tracked by the ventricle. After termination of the extended PVARP, the atrial channel is 'alert' and sensing begins again.

Despite the extended PVARP, the duration of the sensing phase, or the width of the crosstalk sensing window, is set to at least 350 ms, independent of set basic rate and A-V delay. The duration of the sensing phase may be even longer, if the difference between VA delay and extended PVARP, i.e.

$$\text{Sensing Phase} = \frac{1}{\text{Basic Rate}} - \text{AVD} - 500\ \text{ms}$$

(where AVD means the A-V delay) reveals a value exceeding 350 ms.

A sensing phase of at least 350 ms allows atrioventricular synchronization. If the sensing phase terminates without an atrial event sensed, the PACE 203H delivers an atrial stimulus - unless a further ventricular extrasystole has been detected.

9.22.5.2 Subsequent PVCs

If a PVC is followed by another PVC without intermediate atrial sensed or paced event, the behavior is adapted for subsequent PVCs, ensuring appropriate pacing at higher basic rates.

After subsequent PVCs, the PVARP is extended up to 500 ms, but not exceeding

$$\text{PVARP}_{\text{MAX}} = \frac{1}{\text{Basic Rate}} - \text{AVD} - 20\ \text{ms}$$

The maximum PVARP is in agreement with the rules for "abnormal settings" (see 9.22.7).

After subsequent PVCs, the V-A delay is calculated to

$$\text{VA Delay} = \frac{1}{\text{Basic Rate}} - \text{AVD}$$

9.22.5.3 Absolute and relative PVARP

If the patient's heart is beating at a relatively high intrinsic rate, an extended PVARP could have the consequence that, after the recognition of a single extrasystole, subsequent extrasystoles are determined only because within the atrial channel, the PVARP takes up most of the V-A delay.

The PACE 203H avoids this effect by dividing the PVARP in two periods, the absolute PVARP and the relative PVARP. Within the absolute PVARP (90 ms), no atrial events are sensed. Within the relative PVARP (equals the remaining 400 ms), atrial events are sensed, but not tracked by the ventricular channel. Thus, the PACE 203H interprets a ventricular sensed event, following an intrinsic atrial event occurred within the relative PVARP, as a regular beat and not as an extrasystole

As a consequence, ventricular responses caused by premature atrial contractions are not counted as extrasystoles.

9.22.6 Runaway Protection

The PACE 203H can stimulate the heart with a maximum basic rate of 220 ppm or a maximum tracking rate (MTR) of 230 ppm. The output of higher stimulation rates, for example, due to a defect in the frequency generator, is limited by an independent safety function, to a maxi-

mum of 238 ppm. This safety function is referred to as runaway protection.

9.22.7 Protection Against Abnormal Settings

The PACE 203H continuously monitors the setting of parameters so that abnormal settings, as shown in Table 60 can be detected and avoided. Such settings can cause danger for the patient.

Note: All conflicts are avoided, when "Auto A-V Delay", "Auto PVARP" and "Auto MTR" are activated (see chapter 9.9).

Note: The protection against abnormal settings (warning and limitation) can be turned off using the "Alarms on/off" option (see 9.12.5.2). If Alarms are off, it is the responsibility of the user to set appropriate parameter combinations.

Abnormal Settings	Reason for Preventing	Mode	Action
a) Basic Rate > MTR	Basic Rate must not be larger than MTR	DDD VDD DAI VAT DAT	Transient warning message and prevent abnormal setting
b) AVD + PVARP + 20ms > LRI	To guarantee minimum atrial sensing phase	DDD VDD DAI VAT DAT	Transient warning message and prevent abnormal setting
c) AVD + 60ms > LRI	To guarantee minimum VA-delay	D00 DVI	Transient warning message and prevent abnormal setting
d) PVD + PVARP ≥ URI (with URI = 1/MTR)	To guarantee Wenckebach-behavior	DDD VDD DAI VAT DAT	Transient warning message and prevent abnormal setting
e) ARP + 20 ms > LRI	To guarantee minimum atrial sensing phase	AAI AAT	Transient warning message and prevent abnormal settings

Table 60: Abnormal Settings

9.22.7.1 Possible Conflicts

Conflicts can occur in the process of changing parameter settings. In the tables below, all possible cases are listed together with the transient conflict warning message, which will be displayed on the lower display. In case of a conflict, the parameter to be changed is limited to a value still permissible.

The acronyms in the tables have the following definitions:

"↗" = Value to be increased
"↘" = Value to be decreased
"**A**" = Parameter is set to "Automatic Setting"
"**M**" = Parameter is set to "Manual Setting"

Basic Rate	MTR	Message
↗	M	Increase MTR to increase Rate
M	↘	Decrease Rate to decrease MTR

Table 61: Conflicts Type a)

Basic Rate	AVD	PVARP	Message
↗	M	M	Decrease PVARP or AVD to increase Rate
↗	A	M	Decrease PVARP to increase Rate
↗	M	A	Decrease AVD to increase Rate
↘	A	M	Decrease PVARP to decrease Rate
↘	M	A	Decrease AVD to decrease Rate
M	↗	M or A	Decrease PVARP or Rate to increase AVD
M	M or A	↗	Decrease AVD or Rate to increase PVARP

Table 62: Conflicts Type b)

Basic Rate	AVD	Message
↗	M	Decrease AVD to increase Rate
M	↗	Decrease Rate to increase AVD

Table 63: Conflicts Type c)

Basic Rate	AVD (PVD)	PVARP	MTR	Message
↗	M	A	A	Decrease AVD to increase Rate
↗	A	M	A	Decrease PVARP to increase Rate
↗	M	M	A	Decrease PVARP or AVD to increase Rate
↘	M	A	A	Decrease AVD to increase Rate
↘	A	M	A	Decrease PVARP to decrease Rate
↘	A	A	M	Decrease MTR to decrease Rate
↘	M	A	M	Decrease AVD or MTR to decrease Rate
↘	A	M	M	Decrease PVARP or MTR to decrease Rate
M	↗	M or A	M or A	Decrease PVARP or MTR to increase AVD
M	M or A	↗	M or A	Decrease AVD or MTR to increase PVARP
M	M or A	M or A	↗	Decrease PVARP or AVD to increase MTR

Table 64: Conflicts Type d)

Basic Rate	ARP	Message
↗	M	Decrease ARP to increase Rate
M	↗	Decrease Rate to increase ARP

Table 65: Conflicts Type e)

9.22.7.2 Mode Switching

The PACE 203H avoids conflicts as a result of mode switching by selecting appropriate parameter values, according to the rules set for the automatic modes (A-V delay, PVARP and MTR) – independent of whether these automatic modes for the respective parameters are enabled or disabled. The basic rate is the determining parameter and will never be altered. If a conflict type b) (Table 60) must be solved and both PVARP and A-V delay are set to ”manual”, the PACE 203H will, first, set the PVARP to the automatic value (see chapter 9.9.2). If this does not solve the conflict, the A-V delay will be reset to the automatic value (see chapter 9.9.1 The PACE 203H acknowledges that a parameter has been changed appropriately, with regards to the basic rate given, by a short warning message in the lower display.

Example:

AVD
adapted

In this example, the PACE 203H changed the A-V delay.

Note: Because of this maneuver, the PACE 203H does not switch to an automatic mode. The PACE 203H simply determines and sets one or more parameters, similar to what the corresponding automatic mode would have determined.

9.22.8 Effects from Therapeutic and Diagnostic Energy Sources

9.22.8.1 Defibrillation

The PACE 203H is designed in a manner such that it withstands defibrillation discharges according to ISO 14708-1.

Warning: Any protection against defibrillation discharges is limited, due to the low resistance required by the pacemaker output circuitry. In any case, it is mandatory to monitor the patient for a period of time after defibrillation, and to be prepared for a possible failure or malfunctioning of the pacemaker.

To protect the patient and the pacemaker from current passing through the pacemaker / lead-circuit, caused by defibrillation discharges, the stimulation circuit should always be opened, if possible.

Excessively high currents can also damage the pacemaker.

9.22.8.2 RF Surgery

When using RF electrocautery and RF surgery instruments, very strong electrical and magnetic interference is generated which can influence, or even damage, electronic instruments like the PACE 203H. Fibrillation currents can also be generated by crosstalk into the leads and cables.

If simultaneous use of the PACE 203H and electro-surgical instruments is required, the PACE 203H should be set to an asynchronous pacing mode (without any sensing).

Warning: In any case, it is mandatory to continuously monitor the patient, and to be prepared for a possible failure or malfunctioning of the PACE 203H.

9.22.9 Summary of Text Messages

The PACE 203H differentiates between conflicts, application related and device related errors, and warning messages. These are documented in the following sub-sections.

9.22.9.1 Warning Messages Related to Conflicting Parameter Settings

Conflict warnings alert the user that he or she must adjust unusual, conflicting parameter settings. Such settings can result in improper pacing therapy for the patient. The PACE 203H blocks conflicting parameter settings as long as the "Alarms" functions are not disabled (see chapter 9.22.7 and 9.12.5.2).

When the PACE 203H determines a conflict, it displays a warning message in the lower display, accompanied by an acoustic warning signal. The warning message alerts the user about the problem, and how to solve it. Warning messages appear after the recognition of conflicts. Depending on the warning message, it disappears automatically after a few seconds, or after confirmation by the user. The user confirms the warning message by pressing the key **Unlock**/**Lock**. Confirmation causes the warning message to disappear. Table 66 shows a list of these warning messages.

PACE 203H Warning Message	Meaning / Cause	Measures to Eliminate the Conflict / Error	See Chapter
Increase MTR to increase Rate	The user has attempted to increase the rate. This led to a conflict (type a), because MTR is set at an excessively low value.	MTR must be increased or set to "Auto MTR", before the rate can be further increased.	9.22.7
Decrease PVARP or A-V Delay to increase Rate	The user has attempted to increase the rate. This led to a conflict (type b or d), because the sum of PVARP and A-V delay is excessively high.	PVARP and/or A-V delay must be decreased or set to "Auto PVARP" and "Auto AVD" before the rate can be further increased. Alternatively, in case of an implicit conflict (type d) between PVARP plus AVD and automatically set MTR, the manual setting of the MTR to a lower value is suggested.	9.22.7
Decrease A-V Delay to increase Rate	The user has attempted to increase the rate. This led to conflict (type b or c) because the A-V delay is excessively high.	A-V delay must be decreased or set to "Auto AVD", before the rate can be further increased.	9.22.7

PACE 203H Warning Message	Meaning / Cause	Measures to Eliminate the Conflict / Error	See Chapter
Decrease PVARP or Rate to increase A-V Delay	The user has attempted to increase A-V delay. This led to conflict (type b), because there is inadequate time for a long A-V delay in the presence of a high rate and a long PVARP.	PVARP and/or rate must be decreased, before A-V delay can be further increased.	9.22.7
Decrease Rate to increase A-V Delay	The user has attempted to increase A-V delay. This led to conflict (type c), because there is inadequate time for a long A-V delay in the presence of high rate.	The rate must be decreased, before A-V delay can be further increased.	9.22.7
Decrease PVARP or MTR to increase A-V Delay	The user has attempted to increase A-V delay. This led to conflict (type d), because there is inadequate time for a long A-V delay in the presence of a high MTR and a long PVARP.	PVARP and/or MTR must be decreased, before A-V delay can be further increased.	9.22.7
Decrease A-V Delay or Rate to increase PVARP	The user has attempted to increase PVARP. This led to conflict (type b), because there is inadequate time for a long PVARP in the presence of a high rate and a long A-V delay.	A-V delay and/or rate must be decreased, before PVARP can be further increased.	9.22.7
Decrease A-V Delay or MTR to increase PVARP	The user has attempted to increase PVARP. This led to a conflict (type d), because there is inadequate time for a long PVARP in the presence of a high MTR and long A-V delay.	A-V delay and/or MTR must be decreased, before PVARP can be further increased.	9.22.7
Decrease PVARP or A-V Delay to increase MTR	The user has attempted to increase MTR. This led to a conflict (type d), because the sum of PVARP and P-V delay is too long.	PVARP and/or A-V delay must be decreased before MTR can be further increased.	9.22.7

PACE 203H Warning Message	Meaning / Cause	Measures to Eliminate the Conflict / Error	See Chapter
Decrease Rate to decrease MTR	The user has attempted to decrease MTR. This led to a conflict (type a), because rate is set to an excessively high value.	Rate must be decreased, before the MTR can be further decreased.	9.22.7
Decrease PVARP to increase Rate	The user has attempted to increase the rate. This led to a conflict (type b), because the sum of PVARP and A-V delay is too long with respect to the rate or MTR.	PVARP must be decreased or set to "Auto PVARP", before the rate can be further increased. Alternatively, manual setting of the A-V delay or (in case of a conflict type d) MTR to a lower value is suggested.	9.22.7
Decrease A-V Delay to increase Rate	The user has attempted to increase rate. This led to a conflict (type b or d), because the sum of PVARP and A-V delay is too long with respect the rate or MTR.	A-V delay must be decreased or set to "Auto AVD", before the rate can be further increased. Alternatively, manual setting of the PVARP or (in case of a conflict type d) the MTR to a lower value is suggested	9.22.7
Decrease PVARP to decrease Rate	The user has attempted to decrease the rate. This led to a conflict (type b), because the sum of PVARP and A-V delay is too long with respect to rate or MTR.	PVARP must be decreased or set to "Auto PVARP", before the rate can be further decreased. Alternatively, manual setting of the A-V delay or (in case of a conflict type d) the MTR to a lower value is suggested.	9.22.7
Decrease A-V Delay to decrease Rate	The user has attempted to decrease the rate. This led to a conflict (type b or d), because the sum of PVARP and A-V delay is too long with respect to the rate.	The A-V delay must be decreased or set to "Auto AVD", before the rate can be further decreased. Alternatively, manual setting of the PVARP or (in case of a conflict type d) the MTR to a lower value is suggested.	9.22.7
Decrease MTR to decrease Rate	The user has attempted to decrease the rate. This led to a conflict (type d), because the MTR is too high with respect to the sum of PVARP and A-V delay.	The MTR must be decreased or set to "Auto MTR", before the rate can be further decreased. Alternatively, manual setting of the PVARP or of A-V delay to a lower value is suggested.	9.22.7

PACE 203H Warning Message	Meaning / Cause	Measures to Eliminate the Conflict / Error	See Chapter
Decrease A-V Delay or MTR to decrease Rate	The user attempted to decrease the rate. This led to a conflict (type d), because the sum of PVARP, P-V delay and V-V delay is too long with respect to the MTR.	A-V delay and/or MTR must be decreased or set to "Auto AVD" and "Auto MTR", before the rate can be further decreased. Alternatively, manual setting of the PVARP to a lower value is suggested.	9.22.7
Decrease PVARP or MTR to decrease Rate	The user attempted to decrease the rate. This led to a conflict (type d), because the sum of PVARP and A-V delay is too long with respect to the MTR.	PVARP and/or MTR must be decreased or set to "Auto PVARP" and "Auto MTR", before the rate can be further decreased. Alternatively, manual setting of the A-V delay to a lower value is suggested.	9.22.7

Table 66: Warning Messages Related to Conflicting Parameter Settings

9.22.9.2 Warning Messages Related to Application Errors

Generally, if the problem is identified, any application related errors can be solved by the user. Application related errors result in a warning message in the lower display accompanied by an acoustic warning signal, which will be repeated periodically. The warning message alerts the user about the problem. It appears after recognition of the error and disappears after the problem has been solved, or after confirmation by the user. The user can confirm the error message by pressing the key **Unlock**/**Lock**. Confirmation causes the warning message to disappear, and the acoustic signal to cease.

If an error is detected when the lower display is switched off, the acoustic signal is then the only available warning. A first press of the key **Unlock**/**Lock** switches the lower display and the backlight on and unlocks the PACE 203H. The warning message is now visible. A second press of the key **Unlock**/**Lock** then confirms the error message.

If an error is detected when the lower display is switched on, but the device is locked, a first press of the key **Unlock**/**Lock** switches the backlight on and unlocks the PACE 203H. A second press of the key **Unlock**/ then confirms the error message.

The message (except the "... change battery" and the "…lead disconnected" messages) will reappear a few seconds after confirmation, if the error persists. Table 67 shows these messages.

PACE 203H Warning Message	Meaning / Cause	Measures to Eliminate the Conflict / Error	See Chapter
Change battery!	The battery change level is reached. **Note:** This message will be repeated after confirmation every 10 minutes.	Insert a new battery.	9.22.1 11.2
Hurry up! Change battery!	The critical battery change level is reached. Note**:** This message will be repeated after confirmation every 2 minutes.	Insert a new battery.	9.22.1 11.2
Release all keys	A key is pressed while the PACE 203H is turning on.	Release all keys during the power-on process of the device to allow a proper self-test.	9.3
Key timeout	A key is pressed for more than 120 seconds. There is a possibility that something heavy is pressing on the PACE 203H, or it is being abutted against an edge of some sort.	In case no cause is apparent, and the error message persists, this indicates that a key is malfunctioning, and the device must be sent to the manufacturer for inspection and service.	---
Atrial lead disconnected or Ventricular lead disconnected	The atrial lead or ventricular lead has been disconnected. The last stimulation could not be properly carried out. **Note:** This error message will not be repeated after confirmation, even if the disconnection persists. The open output is only indicated by the open lead symbol (see Figure 12). **Note:** Surveillance can only occur, if the stimulation amplitude is set to a value ≥ 2.0 V, and if the pulse duration is ≥ 0.15 milliseconds.	If the lead was not disconnected intentionally, there is a possibility that lead breakage or a disconnection of the connector cable exists. Check all connections, connection cables and leads.	9.22.2

PACE 203H Warning Message	Meaning / Cause	Measures to Eliminate the Conflict / Error	See Chapter
Atrial output short or Ventricular output short	The atrial or ventricular output, respectively, is short-circuited or low-resistance bridged. The PACE 203H was unable to deliver the last stimulation pulse properly. **Note:** Surveillance can only occur, if the stimulation amplitude is set to a value ≥ 2.0 V, and if the pulse duration is ≥ 0.15 milliseconds	Check all connections, connection cables and leads, and identify the short.	9.22.2

Table 67: Warning Messages Related to Application Errors

9.22.9.3 Warning Messages Related to Device Errors

Device related errors are those which are probably caused by a malfunction of the pulse generator itself. (Some may also have external reasons.) Errors of this kind result in a warning message in the lower display, accompanied by an acoustic error signal, which will be repeated periodically. The warning message alerts the user about the problem. It appears after recognition of the error and disappears only after confirmation by the user, i.e. device related error messages *must* be confirmed. (The acoustic error signal will, however, cease when the error is no more present.) The user must confirm the error message by pressing the key **Unlock**/**Lock**. Confirmation causes the text message to disappear and the acoustic signal to cease.

If an error is detected when the lower display is switched off, the acoustic signal is then the only available warning. A first press of the key **Unlock**/**Lock** switches the lower display and the backlight on, and unlocks the PACE 203H. The error warning message is now visible. This is despite the fact that the error no longer present. A second press of the key **Unlock**/**Lock** then confirms the error message.

If an error is detected when the lower display is switched on, but the device is locked, a first press of the key **Unlock**/**Lock** switches the backlight on and unlocks the PACE 203H. A second press of the key **Unlock**/**Lock** then confirms the error message.

If the error persists, the warning message will reappear after confirmation. Table 68 lists the possible warning messages.

PACE 203H Warning Message	Meaning / Cause	Measures to eliminate the Conflict / Error	See Chapter
Unexpected device error no. ### Restart device or submit to inspection	Most of the device related errors are reported by this warning message. The error number "###" can give the manufacturer a helpful hint as to locating the cause of the error. **Note:** The PACE 203H attempts to continue its operation with the current parameter set, or, if this is not possible, with the emergency mode. If the error repeats itself, this may lead to an erratic rhythm.	Attempt to switch the PACE 203H off and, on waiting after a few seconds, on again. If this doesn't solve the problem, remove the battery while the device is switched on, wait for a minimum of 10 minutes and then reinsert. **Note:** The patient must not be connected to the PACE 203H during this maneuver. If the error persists despite of these maneuvers, the PACE 203H must be sent to the manufacturer for inspection and service.	---
Stored data lost! Manufacturer's defaults will be used.	The memory for the Stand-by data and the standard programs has lost its data. The manufacturer's standard turn-on program (see 9.11.5) has been set and all standard programs have been reset to their manufacturer's defaults.	In case this error repeats itself, the PACE 203H must be sent to the manufacturer for inspection and service.	---
Keyboard error	While turning on the device, a key was pressed constantly for more than 10 seconds, despite of the message "Release all keys"	Releasing all keys during the power-on process of the device is necessary to allow a proper self-check. In case all keys were released and the error message persists, this implies that a key is malfunctioning and the PACE 203H must be sent to the manufacturer for inspection and service.	9.3

Table 68: Warning Messages Related to Device Errors

9.22.9.4 Informative Messages

The PACE 203H displays various informative messages on the lower display, which alert the user that certain actions must be taken. These messages are accompanied by an acoustic warning signal and require no confirmation. They disappear automatically after a short period of time or after confirmation by the user. The user can confirm an informative message by pressing the key **Unlock**/**Lock**. Confirmation causes the message to disappear.

PACE 203H Message	Meaning / Cause	Measures to Eliminate the Problem	See Chapter
Startup Timeout (Press Unlock)	The key **Unlock**/**Lock** was not pressed within 30 sec after turning on the pacemaker. **Note**: The PACE 203H will turn itself off after this message.	In order to turn on the pacemaker the key **Unlock**/ **Lock** must be pressed within 30 sec after pressing the key labeled **ON**.	9.3
Auto AVD turned off	The automatic A-V delay setting has been turned off, because the **A-V DLY** dial has been turned.	If the automatic A-V delay setting is to remain enabled, activate it again via the Auto Menu and avoid turning the **A-V DLY** dial.	9.9.1
Atrial Auto Sense turned off	The automatic atrial sensing adjustment has been turned off, because the **A-SENSE SENSE** dial has been turned.	If the automatic atrial sensing adjustment is to remain enabled, activate it again via the Auto Sense Menu and avoid turning the **A-SENSE** dial.	9.9.4
Ventricular Auto Sense turned off	The automatic ventricular sensing adjustment has been turned off, because the **V-SENSE** dial has been turned.	If the automatic ventricular sensing adjustment is to remain enabled, activate it again via the Auto Sense Menu and avoid turning the **V-SENSE** dial.	9.9.4
Switch Atrial Auto Sense off to enable Atrial Trigger	Atrial Auto Sense and Atrial Trigger cannot be enabled at the same time, because the triggered stimulation prevents proper measurement of the intrinsic atrial activation.	Act according to the message.	9.9.4 9.12.5.3

PACE 203H Message	Meaning / Cause	Measures to Eliminate the Problem	See Chapter
Switch Atrial Trigger off to enable Atrial Auto Sense	Atrial Auto Sense and Atrial Trigger cannot be enabled at the same time, because the triggered stimulation prevents proper measurement of the intrinsic atrial activation	Act according to the message.	9.9.4 9.12.5.3
Switch Atrial Auto Sense off to decrease AVD	If atrial Auto Sense is activated, a minimum of 30 ms P-V delay is required to allow proper measurement of the intrinsic atrial activation. Because A-V delay cannot be shorter than P-V delay, it is also limited to 30 ms.	If a shorter A-V delay is necessary, atrial Auto Sense cannot be employed and must be deactivated.	9.9.4
AVD adapted	To resolve a parameter conflict during mode switching, the A-V delay has been changed, i.e., adapted to the current rate*. OR A-V delay has been increased to the minimum value of 30 ms when atrial Auto Sense has been activated.	N/A (conflict resolved by the device). Please check if the altered A-V delay is appropriate for the patient.	9.22.7
PVARP adapted	To resolve a parameter conflict during mode switching, the PVARP has been changed, i.e. adapted to the current rate*.	N/A (conflict resolved by the device). Please check if the altered PVARP is appropriate for the patient.	9.22.7
MTR adapted	To resolve a parameter conflict during mode switching, the maximum tracking rate has been changed, i.e. adapted to the current rate*.	N/A (conflict resolved by the device). Please check if the altered MTR is appropriate for the patient	9.22.7

Table 69: Informative Messages

*) Sometimes only a combination of adaptations resolves the conflict completely. In this case the message reports all adapted parameters.

10 Storage

The storage temperature range of the PACE 203H is –20°C (-4°F)…+60°C (+140°F). Note that the device must be within the operational temperature range before use (+10°C (+50°F)…+45°C (+113°F)).

The enclosed connector cables are sterilized prior to shipment. They are packed in double transparent sterile packages.

The sterilization method is ethylene oxide gas.

The sterility is guaranteed as indicated by the expiration date, if the package is not damaged and properly stored.

The sterile connection cables must be stored in a dry, cool place at temperatures between 10°C (50°F) and 25°C (77°F). Keep out of direct light.

If damage to the package is detected before use, the cable must be repacked in a gas-permeable container and re-sterilized with ethylene oxide gas at a maximum temperature of 50°C (122°F) and a maximum overpressure of 1.7 bar. Sterilization must be accomplished in accordance with the instructions of the gas sterilizer manufacturer. After sterilization, aerate the items before use to permit escape of residual ethylene oxide.

Warning: Connector cables intended for single use must not be re-sterilized after use.

Warning In case the PACE 203H is not to be used for longer periods of time, the battery must be removed in order to prevent damage from possible battery acid leakage. Damage because of a leaking battery is not covered by the manufacturer's guarantee.

11 Care and Maintenance

11.1 Care and Cleaning

As a precision electronic device, the PACE 203H must be handled with corresponding care. Although the device is robustly constructed, it can be damaged by heavy mechanical stress, for example, by dropping on a hard surface.

The enclosure and the keypad of the PACE 203H are protected against accidental liquid spills. To clean the device, use a towel or sponge moistened with water or alcohol.

For disinfection, the enclosure of the PACE 203H can be cleaned with alhydex, cydex, or with detergicide.

Warning: The PACE 203H must not be submerged in either water or in any other cleaning solution. Do not use any scrubbing powder/liquid on the device.

The device must not be sterilized in an autoclave. Sterilization with ultrasound or gamma rays is also not permitted. The PACE 203H can be damaged by such procedures.

The PACE 203H can be sterilized with gas. The battery has to be removed. A temperature of 55 °C and a relative humidity of 90 % must not be exceeded. The pressure must not exceed atmospheric pressure. The procedure given in the instructions for use of the sterilization equipment shall be followed. For validation approved methods must be used.

Re-usable cables must be cleaned, disinfected and sterilized after each use.

Single use cables must not be re-used.

11.2 Changing the Battery

While the device is in use, the battery should be changed when the battery depletion symbol shows only one blinking segment and the warning message *Change battery!* appears. The amount of time remaining from this moment, until the battery is completely drained depends implicitly on the type of battery used, and therefore cannot be predicted with absolute certainty. Typically, one day of reserve energy can be expected with the recommended battery, if the PACE 203H is set to a mode with standard parameters.

During a battery change, the PACE 203H is capable of maintaining continuous operation for at least 30 seconds. Typically, this duration is even longer. The battery change should, therefore, be quick but does not require haste.

Warning: In order to provide continuous operation of the PACE 203H during a battery change, the battery must not remain in the PACE 203H until it is completely drained. During operation of the PACE 203H, the user must not permit the critical depletion level to occur, indicated by battery symbol shown empty and blinking, and the warning message *Hurry up! Change battery!* and then being forced to replace the depleted battery with a new one with great haste.

If the PACE 203H is switched off or to stand-by mode after the request to change the battery appears, the battery must be changed before the PACE 203H is turned on again.

Note: After inserting a new battery, the PACE 203H requires 30 minutes to

recharge its internal power capacitor in order to be able to perform the bridging function again.

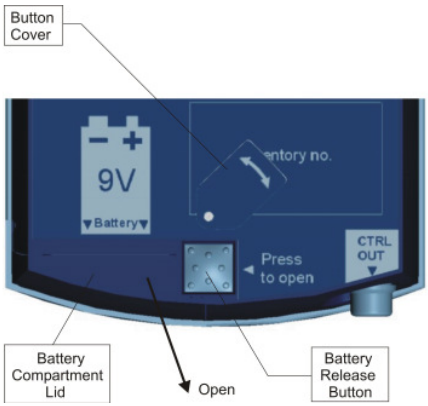


Figure 15: Battery Compartment

For battery replacement, please adhere to the following instructions:

1. Have a new 9 V-battery (6LR61) on hand.
2. On the bottom of the PACE 203H, turn the protection cover of the battery compartment release button, and push the battery compartment release button. Open the battery compartment lid (see Figure 15). Make certain that the inserted battery does not drop on the floor.
3. Remove the battery from the battery compartment.
4. Place a new battery in the compartment. The orientation of the battery polarity is irrelevant.
5. Close the battery compartment lid until it is audibly latched in place. Rotate the protection cover over the battery compartment release button.
6. It is mandatory to dispose of the battery in an environmentally friendly, legal manner.

Warning: Avoid handling with spillage, if the battery compartment is open!

Warning: Only insert a 9 V-battery (6LR61) produced by a respected and reliable battery manufacturer!

11.3 Safety Check-Ups of the Pacemaker

In order to assure safe operation of the PACE 203H, the following check-ups must be carried out on a regular basis.

Before each use

Visual inspection:

- Inspect the device and accessories for visible damage.
- Inspect the connections for visible damage.

Function test

- Inspect all connections to see if they affix and function properly.
- Inspect all operating elements and displays for perfect function.

After each use

- Clean the device and its accessories according to the instructions provided in chapter 1.

Annual Functional and Safety Check

- Measuring the auxiliary currents
- Measuring the stimulation parameters (amplitude, pulse width) in the atrial and ventricular channels
- Measuring the stimulation rate
- Measuring the sensitivity in the atrial and ventricular channel
- Inspecting the battery surveillance and measuring the power maintenance time after removal of battery
- Inspecting the lead surveillance.
- Inspecting the runaway protection

Warning: A repair or calibration made by anyone except the manufacturer or a manufacturer-authorized designee voids the warranty of the PACE 203H.

11.4 Product Return Policy

In the event that a PACE 203H and / or its accessories are defective and / or are beyond repair, the user (customer) must obtain a Return-to-Manufacturer-Authorization (RMA) number from the manufacturer and then return these items to the manufacturer for repair or proper disposal.

12 Customer Service

If you have any questions, the customer service can be reached at:

OSYPKA AG
Earl-H.-Wood-Strasse 1
D-79618 Rheinfelden, Germany
Phone: +49 (7623) 7405 - 0
Fax: +49 (7623) 7405 - 160
E-Mail: mail@osypka.de

For service and repair, please contact the manufacturer:

Osypka Medical GmbH
Albert-Einstein-Strasse 3
D-12489 Berlin, Germany
Phone: + 49 (30) 6392 8300
Fax: + 49 (30) 6392 8301
E-Mail: mail@osypkamed.com

13 Technical Data

PACE 203H Dual Chamber (DDD) Temporary Cardiac Pacemaker

Measurement conditions:	Environment temperature: 20 ± 2°C Voltage supply: 9 ± 0.5 V Load resistance: 500 Ω ± 1% Test impulse: as specified in ISO 14702-8 (Triangle 2 ms / 13 ms)
Pacing modes:	primary: DDD, VVI, AAI, VDD supplementary: D00, V00, A00, DVI, DAI, DDD+AT, DAT
Stimulation indicators:	Yellow LEDs blink synchronous to emission of stimulation pulses
Sensing indicators:	Green LEDs blink synchronous to sensing of P-/R-waves
Basic rate:	30 … 220 ppm ± 2 %
Maximum tracking rate (MTR):	80 … 230 ppm ± 2 %
Atrial overdrive stimulation:	70 … 1000 ppm ± 5 %
Ventricular overdrive stimulation:	180 … 220 ppm ± 2 %
Output pulse:	Cathodic, biphasic, asymmetric, capacitive coupled, passive discharge
Nominal pulse amplitude (500 Ω):	0.1…18 V ± 10 % ± 0.05V V
Nominal pulse amplitude (200 Ω … 2000 Ω):	0.1…18 V ± 20 % ± 0.05V V
Pulse duration:	0.05 ms ... 1.50 ms ± 10 % ± 0.01 ms
Atrial sensitivity:	0.2 … 20 mV ± 20 % ± 0.1 mV, ∞
Ventricular sensitivity:	1.0 … 20 mV ± 20 % ± 0.1 mV, ∞
Input impedance:	22 kΩ ± 20 %
Output impedance:	< 10 Ω
Load impedance range:	200 Ω…2000 Ω
A-V delay (AVD):	5 ms ... 400 ms ± 5 % ± 2 ms (minimum. 30 ms when atrial Auto Sense is activated)

P-V delay (PVD):	Determined by A-V delay – 30 ms (minimum 5 ms when atrial Auto Sense is not activated, minimum 30 ms when atrial Auto Sense is activated); may be prolonged depending on MTR
Escape interval:	Determined by basic rate ± 5 %
Atrial escape interval (V-A delay):	Determined by basic rate and A-V interval ± 5 %
Extended atrial escape interval: (V-A delay after first PVC)	Determined by basic rate and A-V delay (minimum 850 ms) ± 5 %
Atrial Refractory Period (ARP):	250 ms … 400 ms ± 5 % (AAI, AAT); A-V interval plus PVARP (DDD, VDD, DAI, VAT, DAT)
Ventricular Refractory Period (VRP):	250 ms … 500 ms ± 5 %
PVARP:	100 ms ...500 ms ± 5 %
- absolute portion:	90 ms ± 5 %
- relative portion:	PVARP - 90 ms ± 5 %
Extended PVARP (after PVC):	500 ms ± 5 % (or maximum possible period)
Ventricular refractory period:	250 ms ± 5 %
Blanking period in atrial channel:	85 ms ± 5 % + 2 ms / -6 ms after atrial as well as ventricular stimulation and sensing
Blanking period in ventricular channel:	85 ms ± 5 % + 2 ms / - 6 ms after ventricular stimulation and sensing, 55 ms ± 5 % + 2 ms / - 6 ms after atrial stimulation
Discharge period:	45 ms ± 5 % ± 2 ms
Crosstalk detection window:	40 ms
Non-physiologic A-V delay:	100 ms ± 5 % ± 2 ms (for ventricular safety stimulation)
Emergency mode:	V00 (A00), rate 80 ppm, all amplitudes 12 V or set value, when higher, pulse duration atrium 1.0 / ventricles 0.75 ms or set value, when longer, AVD 170 ms (AUTO)

Standard setting:	Standard parameter set for each primary mode, plus one turn-on parameter set
Acoustic signaling:	Different for stimulation, sensing and warnings; stimulation and sensing indication can be turned on or off
Interference detection frequency:	> 4.5 Hz ± 5 % (> 273 bpm)
Interference rate:	Basic rate + 10 ppm ± 2 % (max. MTR and max. 220 ppm)
Defibrillation protection:	According to IEC 60601-2-31
Runaway protection:	238 ppm ± 3 ppm
Lead surveillance:	Message in case of short circuit or interruption in the stimulation circuit (for a set stimulation amplitude equal or higher 2.0 V and a set pulse duration equal or higher 0.15 ms)
Battery:	9 Volt, (identification per IEC 86: 6LR61) Recommended types: Duracell Alkaline MN1604 Sonnenschein Lithium SLM
Life span of recommended battery (Alkaline):	minimal 10 days (VVI, standard parameter) minimal 8 days (DDD, standard parameter)
Life span of recommended battery (Lithium):	minimal 19 days (VVI, standard parameter) minimal 15 days (DDD, standard parameter)
Battery Power Reserve	Plus 1 day reserve after first appearance of the battery change message
Battery depletion indication:	Continuous displaying of battery depletion symbol, blinking of last segment and acoustic warning when the time-to-charge level is reached (7.2 ± 0.2 V), blinking the empty depletion symbol and acoustic warning when an immediate battery change is required (5.5 ± 0.5 V),
Power maintenance during battery change:	Minimum 30 s

Mains operation[4]:	with battery inserted, indication by LED
Operating temperature:	+10 °C (+50 °F)…+45 °C (+113 °F)
Storage temperature (w/o battery):	–20 °C (-4 °F)…+60 °C (+140 °F)
Operation in explosion hazard areas:	The device may not be used in areas where flammable agents are present.
Housing dimensions (L×W×D):	Approx. 200 mm × 96 mm × 38 mm
Overall dimensions (L×W×D):	Approx. 212 mm × 96 mm × 51 mm (with terminals and dials)
Weight without battery:	Approx. 445 g
Weight with battery:	Approx. 490 g
Lead connections:	Protected terminals (collets) for plugs with 0.9 mm – 2.0 mm diameter
Other interface:	Intra-aortic balloon pump interface
Safety standards:	IEC 60601-1, IEC 60601-2-31 Type CF protection against electric shock
EMC standards:	IEC 60601-1-2, IEC 6100-4-2, IEC 61000-4-3 CISPR 11 class B
European Classification	Class IIb according EC-directive 93/42/ECC
US Classification	Class III according 513 FD&C 21 CFR 862-892 [807.87(c)] Product code 74DTE according 21 CFR 870.3600

We reserve the right to make changes without notice.

[4] Option not available in USA and Japan.

14 Delivery Unit

The PACE 203H is delivered in a carrying case with the following content:

- PACE 203H DDD Temporary Cardiac Pacemaker
- 9V Battery
- PACE 203H User's Manual
- PACE 203H Quick Reference Guide

See "Appendix F: PACE 203H Accessories" on page 127 for accessories such as extension cables and adaptors.

15 Conditions of Guarantee and Liability Restrictions

OSYPKA AG warrants each new PACE 203H (excluding batteries) to be free from defects in materials and workmanship for a period of two (2) years following delivery of the unit to the original purchaser. If our examination of the PACE 203H discloses a defect to our reasonable satisfaction, then we will repair or replace the defective parts or unit, at our discretion. If it is not possible to repair or replace the PACE 203H, we will substitute a functionally equivalent device or refund your original purchase price, at our discretion.

For Warranty claims, the defective unit must be returned within thirty (30) days after discovery of the defect, postage or shipping prepaid and the RMA number displayed, to:

OSYPKA AG
Earl-H.-Wood-Strasse 1
D-79618 Rheinfelden
Germany

If you mail or ship your PACE 203H to us, we recommend that you insure and/or track your shipment since we will not be liable for loss or damage during shipment.

This warranty does not cover: (1) incidental or consequential damages (including but not limited to medical expenses) caused by a defect or malfunction, whether your claim is based on warranty, contract, tort, or otherwise; (2) damage from accident, abuse, misuse, or introduction of foreign objects; (3) unauthorized modifications, alterations or repairs; (4) failure to follow the manufacturer's instructions; (5) third-party actions (fire, vandalism, theft, etc.); (6) the elements or acts of God; (7) accessories; (8) preventative maintenance; (9) damage that is not reported with 30 days after expiration of the Warranty; (10) external electrical interference; (11) shipping and mailing costs; (12) batteries.

THIS WARRANTY IS ESPRESSLY IN LIEU OF ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE REMEDIES SET FORTH IN THIS WARRANTY SHALL BE THE ONLY REMEDIES AVAILABLE TO ANY PERSON. NO PERSON HAS ANY AUTHORITY TO BIND US TO ANY REPRESENTATION OR WARRANTY EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

This Warranty, including its terms, conditions, limitations, exceptions and exclusions, contains our entire obligation to you, and replaces any other representations made to you or understanding you may have about our obligation. You may also have additional rights that vary from state to state.

16 Appendix A: Glossary

Atrial escape interval	Time between ventricular sensed beat or a ventricular pulse and the succeeding non-triggered atrial pulse of a pulse generator, i.e. the time when the pacemaker waits for a P-wave.
Atrial tracking	In an atrioventricular mode, a ventricular stimulus tracks a detected atrial P-wave (after P-V delay) up to the programmed maximum tracking rate. This results in an atrial controlled timing of the pacemaker.
Atrial triggering	A detected P-wave causes an atrial stimulus.
Atrioventricular interval (AVI)	Delay between an atrial pulse or the sensing of an atrial depolarization and the subsequent ventricular pulse or the sensing of a ventricular depolarization. The actual AVI can be shorter than the adjusted A-V delay or P-V delay in case of a spontaneous ventricular depolarization.
A-V crosstalk	Detection of the atrial output pulse by the ventricular sensing amplifier which may result in ventricular output inhibition.
A-V delay (AVD)	Programmed delay between an atrial pulse and the subsequent non-triggered ventricular pulse under the condition that no sensing of a ventricular depolarization was detected by the pulse generator.
Basic rate (short: rate)	Pulse rate of a pulse generator, either atrial or ventricular, unmodified by sensed cardiac or other electrical influence.
Basic pulse interval	Pulse interval unmodified by sensed cardiac or other electrical influence. Basic pulse interval = 1 / basic rate.
Blanking period	Period during which a sensing function of a pulse generator is disabled.

Cross blanking period	Period during which the sensing function of the pulse generator is disabled in one channel because of an event in the other channel.
Escape interval	Time between a sensed beat or a pulse and the succeeding non-triggered pulse of a pulse generator.
External pacemaker	Non-Implantable pulse generator and patient cables (if used).
Inhibition	The effect of the pulse suppression in a demand-pacemaker at sensing of a cardiac depolarization or other electrical influence in the same chamber.
Interference pulse rate	Pulse rate with which the pulse generator responds when it senses electrical activity other than that from the myocardium and recognizes that as interference.
Lower rate interval (LRI)	The longest period between consecutive (paced or sensed) events occurring in the relevant chamber. (In absence of sensed cardiac or other electrical influence: equal to basic pulse interval.)
Maximum tracking rate (upper rate, MTR)	Maximum ventricular pacing rate in response to sensed atrial activity. Expressed differently it is the maximum pulse rate at which the non-implantable pulse generator will respond on a 1:1 basis to a triggering signal.
Non-implantable pulse generator	Medical electrical equipment with an internal electrical power source which is intended for use outside the body and which produces a periodic electrical pulse intended to stimulate the heart through a lead (or combination of lead and patient cable).
Patient Cable	Device attached to the terminals of a non-implantable pulse generator so that the distance between it and the pacing lead can be increased.

Post-ventricular atrial refractory period (PVARP)	Period after a ventricular event (whether sensed or paced), during which synchronous ventricular pacing is disabled, regardless of any atrial event. The PVARP of the PACE 203H is divided in two periods: an absolute period and a relative period. In the absolute period (90 ms) no atrial events are recognized. In the relative period (the remaining) atrial events are registered, but not tracked. This algorithm prevents misinterpretation of ventricular events after premature atrial events as extrasystoles (PVCs).
Premature ventricular contraction (PVC)	A sensed ventricular event not preceded by a sensed atrial event. Also named extrasystole.
Pulse	(Monophasic) electrical output of a pulse generator intended to stimulate the myocardium.
Pulse amplitude	Magnitude of the pulse expressed in volts or milliamperes.
Pulse duration	Duration of the pulse.
Pulse interval	Time interval between identical points of two consecutive pulses, expressed in milliseconds.
Pulse rate	Number of pulses per minute 1 ppm = 1/60 s^{-1}
P-V delay (PVD)	Delay between the sensing of an atrial depolarization and the subsequent non-triggered ventricular pulse under the condition that no sensing of a ventricular depolarization was detected by the pulse generator.
Refractory period	Period during which a pulse generator will not respond to a beat.
Sensitivity	Minimum signal, expressed in millivolts, required to consistently control the function of the pulse generator.
Upper rate interval (URI)	The shortest period allowable between paced or sensed events, while still maintaining 1:1 atrioventricular synchrony (equal to 60 / MTR_{ppm}).

V-A delay (VAD)	Other expression for atrial escape interval.
Ventriculoatrial interval (VAI)	Delay between a ventricular pulse or the sensing of a ventricular depolarization and the subsequent atrial pulse or the sensing of an atrial depolarization.

17 Appendix B: Menu Tree

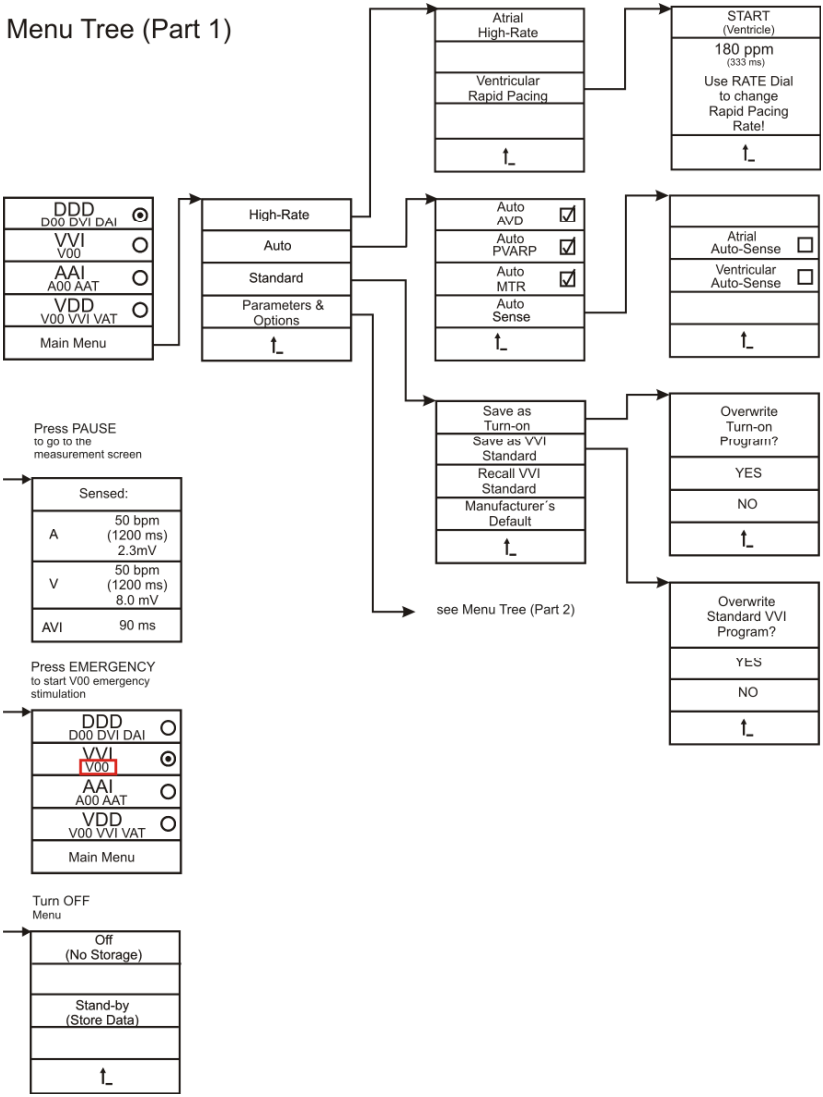


Figure 16: Graphical Schema of Menu Tree (Part 1)

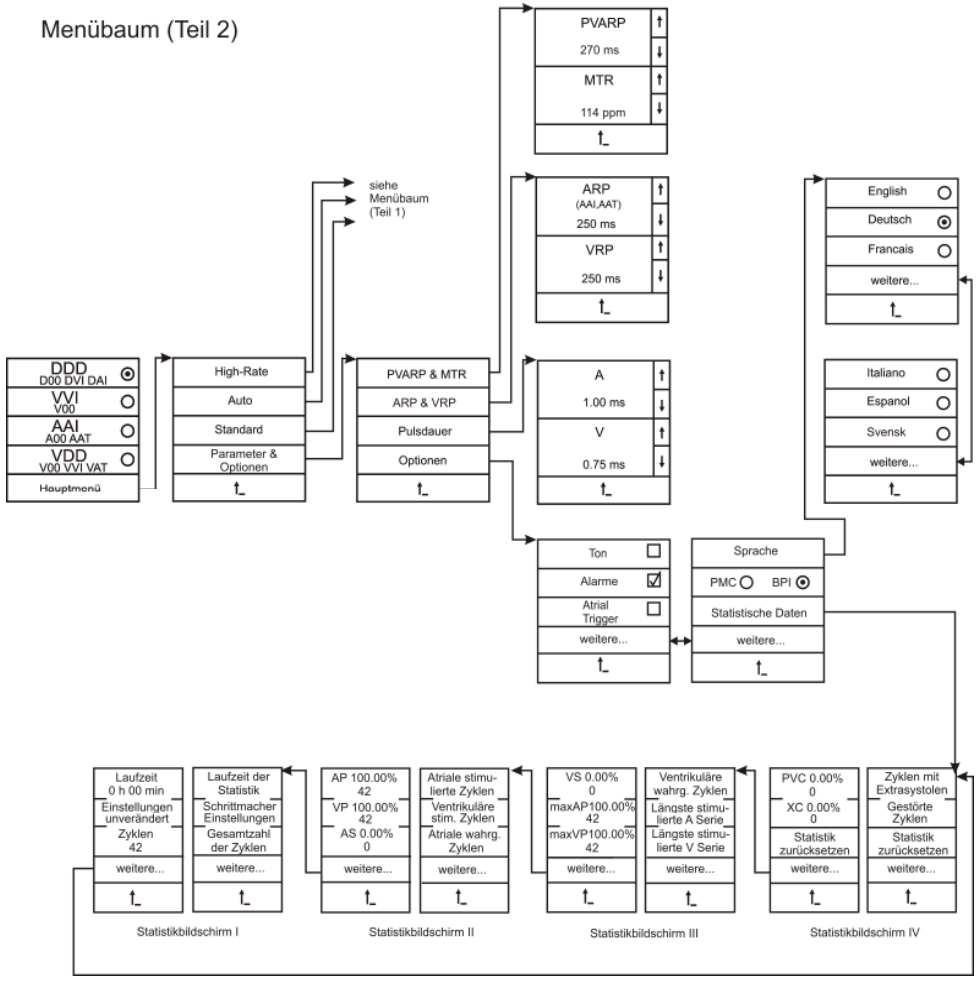


Figure 17: Graphical Schema of Menu Tree (Part 2)

18 Appendix C: EMC Guidance and Manufacturer's Declaration

The PACE 203H needs like every medical electrical device special precautions regarding electromagnetic compatibility (EMC). This section is intended to give the user guidance and information about all aspects to ensure that the PACE 203H operates as intended in an electromagnetic environment. Guidance here given must be followed for putting PACE 203H into service.

The user must be aware that the use of leads and patient cables other than those specified in the instruction for use may result in increased electromagnetic emissions or decreased electromagnetic immunity.

The PACE 203H should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the PACE 203H should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Emission

Table 70 states the compliance classification for electromagnetic emissions and describes the general electromagnetic environment that the PACE 203H is intended to operate in.

Guidance and manufacturer's declaration – electromagnetic emissions		
The PACE 203H is intended in the electromagnetic environment specified below. The customer and the user of the PACE 203H should assure that it will be used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The PACE 203H uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PACE 203H is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Table 70: Guidance and manufacturer's declaration – electromagnetic emission

Electromagnetic Immunity

Table 71 states the immunity test and compliance level for electrostatic discharge and power frequency magnetic fields and describes the electromagnetic environment that the PACE 203H is intended to operate in.

Guidance and manufacturer's declaration – electromagnetic immunity			
The PACE 203H is intended in the electromagnetic environment specified below. The customer and the user of the PACE 203H should assure that it will be used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8, ± 15 kV air	± 6 kV contact ± 8, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable for input/output lines	Mains power quality should be that of typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable	No applicable (PACE 203H has an uninterruptible power system)
Power frequency magnetic field	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE U_T is the AC voltage prior to application of the test level			

Table 71: Guidance and manufacturer's declaration – electromagnetic immunity I

The following Table 72 states the immunity test and compliance level for radiated RF electromagnetic fields. Guidance is given for the electromagnetic environment regarding those fields.

Guidance and manufacturer's declaration – electromagnetic immunity			
The PACE 203H is intended in the electromagnetic environment specified below. The customer and the user of the PACE 203H should assure that it will be used in such an environment.			
Immunity test	IEC 60601 test level	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	10 Vrms 150 KHz to 80 MHz outside ISM bands[a] 10 Vrms 150 KHz to 80 MHz in ISM bands[a] 10 V/m 80 MHz to 2.5 GHz	10 Vrms 150 KHz to 80 MHz outside ISM bands[a] 10 Vrms 150 KHz to 80 MHz in ISM bands[a] 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PACE 203H, including cables and leads, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{12}{V_2}\right]\sqrt{P}$ $d = [1.2]\sqrt{P}$ 80 MHz to 800 MHz $d = [2.3]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W)

			according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).[b] Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 150 KHz and 80 MHz are 6.765 MHz to 6,798 MHz;
13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b The compliance levels in the ISM frequency bands between 150 KHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency range

c Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PACE 203H is used exceeds the applicable RF compliance level above, the PACE 203H should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PACE 203H.

d Over the frequency range 150 KHz to 80 MHz, field strengths should be 10 V/m.

Table 72: Guidance and manufacturer's declaration – electromagnetic immunity II

Table 73 lists minimum separation distances between PACE 203H and portable / mobile RF communication equipment that should be maintained to avoid interference.

Recommended separation distances between
portable and mobile RF communication equipment

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the PACE 203H can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PACE 203H as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m			
	150 KHz to 80 MHz outside ISM bands $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**150 KHz to 80 MHz in ISM bands** $d = \left[\frac{12}{V_2}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = [1.2]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [2.3]\sqrt{P}$
0.01	0.04	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.1	3.8	3.8	7.3
100	3.5	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distances *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 KHz and 80 MHz are 6.765 MHz to 6,798 MHz;
13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 KHz and 80 MHz and in the frequency range 80 MHZ to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 73: Distances between portable and mobile RF communication equipment

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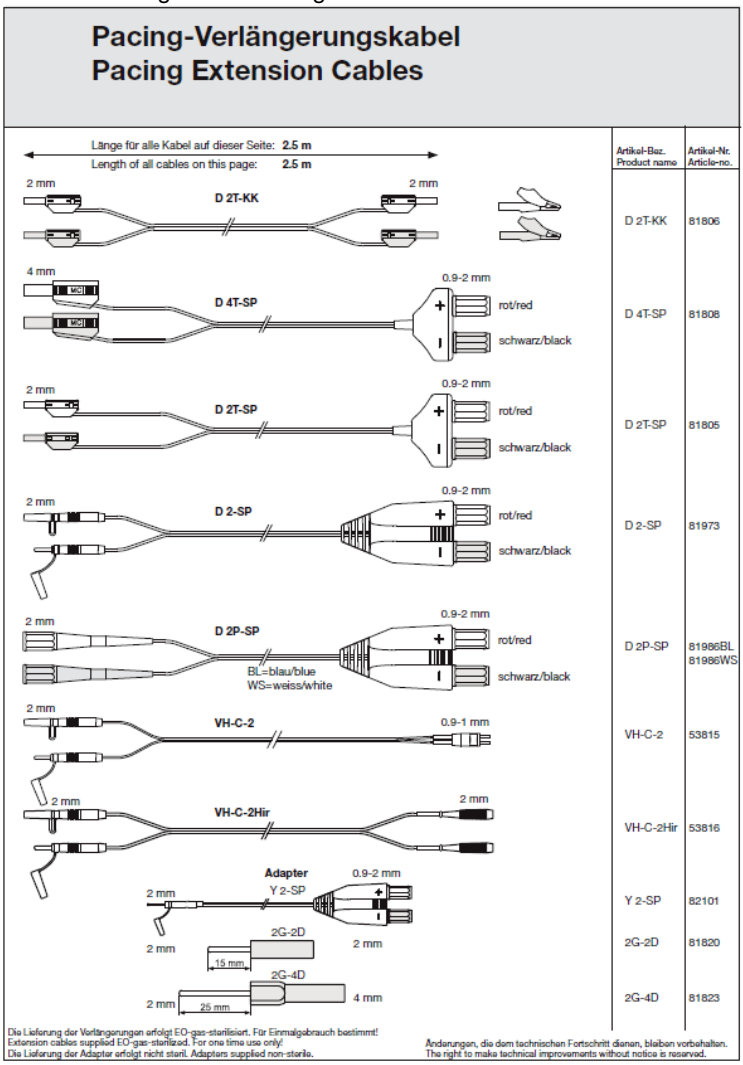
21 Appendix F: PACE 203H Accessories

Please contact OSYPKA AG (address on title page) for accessories available for the PACE 203H, such as various types of extension cables, adapters, and the BPI 202 interface for an intra-aortic balloon pump.

Figure 18: Pacing Extension Cables



22 Appendix G: Declaration of Conformity

We,

Osypka Medical GmbH
Albert-Einstein-Strasse 3
12489 Berlin
Germany

declare under our sole responsibility, that the medical device

Dual-chamber External Pacemaker PACE 203™
including Power Supply PACE and accessories

is in conformity with the act on Medical Devices, the Medical Device Directive 93/42/EEC amended by 2007/47/EC with reference to Directive 2006/42/EC on Machinery and the applicable medical device standards IEC 60601 - 1 and IEC 60601-2-31.

This Declaration of Conformity covers all in our company manufactured loads of the above mentioned device, which are labelled with the CE mark.

This Declaration of Conformity is based on the Full Quality Assurance System certification with the registration number G1 10 04 39212 013 issued by the Notified Body Nr. 0123, the TÜV Product Service GmbH in Munich.

Berlin, 2010/06/21

Plant Manager

Quality Manager